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.	

<u>Project Team Info.</u>

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)	Free Text Field
3.2	Enter the Principal Investigator's secondary appointments or affiliations (including Post-Secondary and Health Authorities) if applicable	Free Text Field
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.	Free Text Field
3.4	Please confirm all research team members have completed the required TCPS 2 Tutorial.	I confirm all research team members have completed TCPS2 Tutorial Not confirmed at time of submission
3.5	Please describe any special training requirements or qualifications required for the study team to conduct the study.	Free Text Field

4. Study Funding Information

#	Question	Answer
4.1	Please provide the funding title (if different than the project title). (N/A if not applicable)	Free Text Field
4.2	Please list the type of funding for this research study.	For Profit Sponsor (Includes pharmaceutical or clinical trial industry or grants from either) Not-For-Profit Grant Internal Funds No Funding N/A Other
4.3	If other, please describe	Free Text Field
4.4	Please provide the name of the funding agency, department or industry sponsor. (N/A if not applicable)	Free Text Field
4.5	For funded studies, please provide name of the institution where the funds will be held. N/A if not applicable	US Department of Health and Human Services (DHHS) National Health Institute (NIH) Department of Justice Other
4.6	Enter any applicable information about your funding which is not already included (including funding applied for but not yet received).	Free Text Field
4.7	Is the study funded by the US Department of Health and Human Services (DHHS)?	Free Text Field
4.8	If yes, to above, please indicate which DHHS funding agency.	Free Text Field

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.	Yes No
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.	Yes, please complete this section No, go to the next tab in the application Unsure? Please contact the Manager, Research Ethics and Compliance, Elizabeth.Bennett@islandhealth.ca
5.3	Please describe the conflict of interest (COI) including dollar value where applicable.	Free Text Field
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,	Yes No

	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	Free Text Field
5.6	Please advise how you propose to manage any actual, perceived, or potential COI outlined above.	Free Text Field
5.7	If applicable, please identify mitigation for any possible 'power over' relationships.	Free Text Field

6. Study Type

#	Question	Answer
6.1	Indicate whether your application is a Retrospective Chart Review or Health-Behavioural	Retrospective Chart Review, please skip to the next tab Health-Behavioural Study, Please skip to the next tab
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.	Free Text Field
7.2	If applicable, please describe the relationships between this proposal and the previously/simultaneously submitted proposal listed above.	Free Text Field
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.	Yes, please add relevant documentation under Attachments No
7.4	Peer Review -- Has the research proposal received any independent scientific/methodological peer review? All above minimal risk studies require a peer review.	Yes, provide details below No
7.5	External peer review details including name of individual:	Free Text Field
7.6	Internal peer review details including name of individual:	Free Text Field
7.7	If this research proposal has NOT received any independent scientific/methodological peer review, explain why no review has taken place:	Free Text Field
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.	Yes, Minimal Risk No, Above Minimal Risk Not sure, please contact the Research Ethics office at ResearchEthics@islandhealth.ca

7.9	Provide an explanation for the assessment of research risk and group vulnerability reported above.	Free Text Field
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.	Free Text Field
7.11	Does this study require review and approval by another Canadian REB outside of Research Ethics British Columbia (REBC)?	Free Text Field

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.	Free Text Field
8.2	Summarize the research proposal including study purpose, hypothesis, study population, and research method.	Free Text Field
8.3	Inclusion Criteria - Describe the participants being selected for this study, and list the criteria for their inclusion.	Free Text Field
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.	Free Text Field
8.5	Recruitment -- Provide a detailed description of the steps you will use to recruit participants. Include: Who will contact the prospective participants	Free Text Field
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.)?	Free Text Field
8.7	Recruitment -- Provide a detailed description of the steps you will use to recruit participants. Include: How will prospective participants be identified	Free Text Field
8.8	Recruitment -- Provide a detailed description of the steps you will use to recruit participants. Include: all site specific information.	Free Text Field

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.	Free Text Field
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.	Free Text Field
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.	Free Text Field
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'	Action research (researchers investigating their own practice Autobiography/Auto-Ethnography Community Based Research (collaboration with community on design and methods) Data Linkage Deception Ethnographic Fieldwork Expert Interviews Focus Groups Masters Research Naturalistic Observation Participant Pools PhD Dissertation Research Random Digit Dialing Secondary Use of Data Snowball Sampling Undergraduate Research Use of Medical Records Video or Audio taping None of these methods Other
8.13	If other, please describe:	Free Text Field

9. Participant Information and Consent Process

#	Question	Answer
9.1	How much time will a participant be asked to dedicate to the project?	Free Text Field
9.2	Describe what is known about the risks of the proposed research for participants and how it will be mitigated.	Free Text Field
9.3	Describe any potential benefits to the participant that could arise from participation in the proposed research.	Free Text Field
9.4	If your research involves an identified group or community, outline the likely impacts of the research on the community.	Free Text Field
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.	Free Text Field
9.6	If applicable please describe the community consent process. If no community consent is being sought, please justify.	Free Text Field
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.	Free Text Field
9.8	Obtaining Consent - Include details of where and when consent will be obtained and how it will be documented.	Free Text Field
9.9	If you are asking for a waiver or an alteration of the requirement for participant informed	Free Text Field

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

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

#	Question	Answer
10.1	Does this research focus on Indigenous peoples, communities or organizations?	Free Text Field
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?	Free Text Field
10.3	Do any of the criteria for participation include membership in an Indigenous community, group of communities, or organization, including urban Indigenous populations?	Free Text Field
10.4	Does the research seek input from participants regarding a community's cultural heritage, artifacts, traditional knowledge or unique characteristics?	Free Text Field
10.5	Will Indigenous identity or membership in an Indigenous community be used as a variable for the purposes of analysis?	Free Text Field
10.6	Will the results of the research refer to Indigenous communities, peoples, language, history or culture?	Free Text Field
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?	Free Text Field
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	Free Text Field

	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.	Free Text Field
10.10	If your research involves an identified group or community, outline the likely impacts of the research on the community.	Free Text Field
10.11	If applicable please describe the community consent process. If no community consent is being sought, please justify.	Free Text Field
10.12	Registration for Publication of Clinical Trials	Yes No
10.13	If yes, please enter the following information: Has the study been registered?	Free Text Field
10.14	Authorized Registry used:	Free Text Field
10.15	Clinical Trial unique identifier:	Free Text Field
10.16	Number of Participants -- How many participants will take part in the entire study (eg. World-Wide)?	Free Text Field
10.17	How many participants will take part at institutions covered by this Research Ethics approval?	Free Text Field
10.18	Principal Investigator and Research Team Experience:	Free Text Field

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

#	Question	Answer
11.1	Please select all tools for data collection.	Surveys Questionnaires Case report forms Interviews Group Activity Other
11.2	If other, please describe:	Free Text Field
11.3	Please describe who on the study team will be doing the data collection:	Free Text Field
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.	Free Text Field
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.	Free Text Field
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.	Free Text Field
11.7	Will any personal health information or personal identifiers be collected?	Yes No

11.8	If yes, please describe what personal identifying information will be collected, and justify the need for it to be collected.	Free Text Field
11.9	How and where will data be stored? (E.g., computerized files, hard copy, videotape, audio recordings, personal electronic communications device, other.)	Free Text Field
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.	Free Text Field
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.	Free Text Field
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.	Free Text Field
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.	Free Text Field
11.14	Describe the safeguards in place to protect the confidentiality and security of the data:	Free Text Field
11.15	If any data or images are to be kept on the Web, what precautions have been taken to prevent them being copied?	Free Text Field
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)	Free Text Field
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.	Free Text Field
11.18	Is this application for research requiring access to clinical charts OR data from registries or databases such as PopDataBC or Pharmanet?	Yes No

11.19	If data will be collected from health records at Island Health, please identify, by name, who will be accessing the health record.	Free Text Field
11.20	Insert the date range of the charts/data to be included in the research:	Free Text Field

12. Retrospective Chart Review

#	Question	Answer
12.1	Is this a retrospective chart review study for which participant consent will be obtained?	Yes No
12.2	Describe how permission to access the medical records and to collect and use these records will be obtained.	Free Text Field
12.3	Briefly describe the type of data that you intend to collect (e.g., disease, diagnosis, outcome, demographic, aggregate, personal-level).	Free Text Field
12.4	Number of Records/Patient Charts	Free Text Field
12.5	Are you collecting and retaining personally identifiable information to be a part of the data set?	Yes No
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.	Free Text Field
12.7	Please explain if and why the identifiable information essential to the research.	Free Text Field
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.	Free Text Field

12.9	Please explain how the researchers will take appropriate measures to protect the privacy of individuals and to safeguard the identifiable information.	Free Text Field
12.10	Please explain how the researchers will comply with any known preferences previously expressed by individuals about any use of their information.	Free Text Field
12.11	Please explain why it is impossible or impracticable to seek consent from individuals to whom the information relates.	Free Text Field
12.12	Please describe how the researchers will obtain any other necessary permissions for secondary use of the information for research purposes.	Free Text Field
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.	Free Text Field
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.	Free Text Field
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.	Free Text Field
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)	Free Text Field
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.	Free Text Field
12.18	Will data be transferred out of the custody and control of Island Health?	Yes No

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.	Free Text Field
12.20	Do you plan to link the data to any other data?	Yes No
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.	Free Text Field

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.	Yes I would like more information
13.2	I agree to conduct the study in accordance with the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans 2nd Edition (2014)	Yes I would like more information
13.3	I agree to conduct the study in accordance with the REB approved documents.	Yes I would like more information
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	Yes I would like more information
13.5	I agree that Island Health may conduct a compliance audit of this study.	Yes I would like more information
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.	Free Text Field

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

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
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.	Free Text Field
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.	Free Text Field
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.	Free Text Field