2023 Operational Review to Conduct a Research Project at Island Health V23

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. Application for Operational Approval to Conduc ...

2. 2. Project Information

#	Question	Answer
2.1	Research Project Title:	
2.2	REB/RISe File Number:	
2.3	Island Health Collaborator: Name, Address, Telephone and Email.	
2.4	Primary Contact Person: Name, Address, Phone and Email.	
2.5	Study summary - Summarize the research proposal: Purpose, Hypothesis, Justification, Objectives, Research Design, and Statistical Analysis.	
2.6	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.	
2.7	How many participants (including controls) will be enrolled at the institutions covered by this Research Ethics Approval?	
2.8	Will you or any of your research team members access identifiable person information of Island Health patients, clients, residents, and/or staff in this research project? Please describe:	
2.9	If Island Health staff/physicians will be involved in the recruitment of participants for the study, please describe what the involvement will entail.	
2.10	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.	
2.11	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.	
2.12	Type of Study:	
2.13	If other, please describe:	

3. 3. Funding Information

#	Question	Answer

3.1	Is the study funded? If there is no funding, please skip to the next tab.	
3.2	Name of Funding Agency (or Agencies):	
3.3	Please provide the name of the institution where the funds will be held:	
3.4	Type of Funding Source:	
3.5	If other, please describe:	

4. 4. Island Health Departments

#	Question	Answer
4.1	Island Health Departments impacted by this research project - check all that apply:	
4.2	Island Health database (PACS, ORMIS) or other, please describe:	
4.3	Please describe any additional information not found in the list of departments that you require access to at Island Health:	
4.4	Please attach the Departmental Cost Analysis or Cost and Support Letter from each department impacted by your research:	

5. 5. Health Records

#	Question	Answer
5.1	Does this study require access to Health Records (either electronic health record, paper charts or outpatient clinic records)? If no, please skip to next tab.	
5.2	Confirm that any medical records that require review by a non-Island Health study team member (study sponsor in a clinical trial for example):	
5.3	Confirm that any medical records that require review by a study team member who is not an employee of Island Health (Study Sponsor in a clinical trial for example will be requested in advanced and will be reviewed onsite:	
5.4	Please enter the name, phone number and email address for the Study Coordinator:	
5.5	Please submit billing invoice to (name and address) if different from above:	
5.6	Please select the most accurate statement regarding your study:	
5.7	Anticipated data collection start date:	

5.8	Anticipated end date:	
5.9	Will you require access to patient medical records (charts) located in an Island Health Health Information Management Department?	
5.10	Number of Health Records required:	
5.11	If known, please advise: where the patient records are located (clinic/ward/department or community site):	
5.12	Who will be pulling the charts and providing them to the researchers:	
5.13	Is this a retrospect chart review study for which participant consent will be obtained?	
5.14	Describe how permission to access the medical records and to collect and use these records will be obtained.	
5.15	The name of the study, a copy of the Island Health Institutional Approval (including the Certificate of Ethical Approval). And the signed consent form for each participant must be attached to the chart requests. You will be invoiced at the completion of the study as per costing letter obtained.	

6. 6. Decision Support and Databases

#	Question	Answer
6.1	Will this research project involve the services of Decision Support or access to an Island Health database? If no, please skip to the next tab.	
6.2	Briefly describe the type of data that you intend to collect (eg. disease, diagnosis, outcome, demographic, aggregate, personal-level)	
6.3	Are you collecting and retaining personally identifiable information to be a part of the data set?	
6.4	Indicate what personally identifying information you will be collecting and retaining as part of the data set. Include a justification of why it is required.	

6.5	Please explain if you are collecting personally identifying formation, and provide a justification as to why the identifiable information is essential to the research.	
6.6	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.	
6.7	Please explain how the researcher will take appropriate measures to protect the privacy of individuals and to safeguard the identifiable information.	
6.8	Please explain how the researchers will comply with any known preferences previously expressed by individuals about any use of their information.	
6.9	Please explain why it is impossible or impracticable to seek consent from individuals to whom the information relates.	
6.10	Please describe how the researchers will obtain any other necessary permissions for secondary use of the information for research purposes.	
6.11	Describe how the identity of the participants will be protected both during and after the research project, including how the participants will be identified on data collection forms.	
6.12	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.	
6.13	Describe how and where the data will be stored (eg computerized files, hard copy, video recording, audio recording, personal digital device, other).	

6.14	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.	
6.15	Will data be transferred out of the custody and control of Island Health?	
6.16	If data will be transferred out of Island Health, please describe: 1. The type of data to be transferred, 2. Who the data will be transferred to, 3. Where the data will be transferred and, 4. How the data will be sent.	
6.17	Do you plan to link the data to any other data?	
6.18	If yes: 1. Identify the data set 2. How the linkage will occur 3. Provide a list of data items in the other database 4. Identify what personal information will be used to link the databases and, 5. How confidentiality regarding this shared information will be preserved.	
6.19	If you are receiving data from Decision Support please list contact information of patients to be provided and used for recruitment purposes.	
6.20	Will you require access to data from a database or clinical system in connection with this research project (eg Island Health database such as PowerChart, PACS, ORMIS, PARIS or an internal/department database such as the Orthopedic Trauma Database)?	
6.21	If yes, please list the databases you will require access to:	
6.22	Please obtain the approval from the applicable data steward(s), please upload approvals to the attachments tab.	
6.23	Will contact information of patients be extracted from an Island Health Data source and used for recruitment purposes?	

6.24	If yes, have the patients consented to be contacted for future research?	

7. 7. Contracts and Agreements

#	Question	Answer
7.1	Will this study lead to commercialization or a patent application.	
7.2	Will there be 3rd party access to Island Health systems or data within Island Health?	
7.3	Will data be transferred out of Island Health?	
7.4	If yes, where is data being transferred?	
7.5	Are Human samples being transferred out of Island Health?	
7.6	If yes, where are samples being transferred?	
7.7	Is this a clinical trial?	
7.8	Will non-Island Health personnel need to access Island Health facilities/services for a study component?	
7.9	If yes, please enter a brief description.	
7.10	Do you wish to form a research collaboration with Island Health?	
7.11	If yes, please describe.	

8. 8. Privacy and Compliance

#	Question	Answer
8.1	Does your study require any member of the study team to access an Island Health system, (such as the Electronic Health Record).	
8.2	If yes, 1. What system do you want access to,2. Which study team members will need access to the system(s)?	
8.3	Are you requesting data to leave Island Health without participant consent? (for example will Island Health provide a data extract which will be stored at another organization by the research team)	
8.4	Are you implementing any new systems hardware, software, or infrastructure at Island Health to support your research? (e.g. Registries, biobanks)	

8.5	Are there Island Health study team members (e.g. Physicians, employees, contractors)?	

9. 9. Laboratory Medicine

#	Question	Answer
9.1	Are Laboratory Services provided by Island Health required for this study? If no, please skip to the next tab.	
9.2	Please enter the name phone number and email address of the study coordinator:	
9.3	Submit billing invoice to: (name, address, email address) if different from above.	
9.4	Please ensure a copy of the lab manual for the study is included in the attachments tab.	
9.5	If no, please explain.	
9.6	Number of participants that require lab:	
9.7	Number of lab collections per study participant:	
9.8	Are the participants:	
9.9	Specimen types:	
9.10	If other specimen type, please describe.	
9.11	Is local analysis required?	
9.12	Please list the tests to be performed by local Island Health lab, (only list above standard of care)	
9.13	Are any test required on a STAT basis?	
9.14	If yes, please name the test.	
9.15	If samples are to be sent to another lab for analysis, please identify who will be responsible for packaging and shipping:	
9.16	Please describe the shipping requirements for the other lab:	
9.17	Name and address of other lab (if applicable):	
9.18	If shipping to be done by Island Health lab, who will provide the shipping supplies	
9.19	If a specific courier service is required, please provide details:	

10. 10. Medical Imaging

#	Question	Answer
10.1	Are Medical Imaging services required for this study? If no, please skip to the next tab	

10.2	Please enter the name, phone number and email address of the study coordinator:	
10.3	Submit billing invoice to (name and address if different from above):	
10.4	Attach any manuals or study specific documents pertaining to Medical Imaging requirements under the attachments tab.	
10.5	If not attached, please explain:	
10.6	Number of participants that will require Medical Imaging:	
10.7	Number of exams/scans per participant or attach a schedule of events under the attachments tab.	
10.8	Are the participants:	
10.9	Modality types:	
10.10	Please describe the type of exam and if contrast is required.	
10.11	Will results have:	
10.12	Please list above standard-of-care exams required:	
10.13	Are any exams required on a STAT basis?	
10.14	If yes, please specify exam name:	
10.15	Are tumor measurements required for every CT scan? (where applicable)	
10.16	How are tumor measurements required to be performed? Eg RECIST 1.1	
10.17	Is a Bone Scan Assessment Worksheet required?	
10.18	If yes, please include this in the attachments tab.	
10.19	If no, please explain.	
10.20	Please describe your proposed process to send images.	

11. 11. Heart Health

#	Question	Answer
11.1	Will services provided by Heart Health unit be required for the study? If no, please skip this tab.	
11.2	Please enter the name, phone number and email address of the Study Coordinator:	
11.3	Submit billing invoice (name and address) if different from above.	
11.4	Please indicate the number of participants:	
11.5	Number of exams per participant or attach a schedule of events:	

11.6	Are the participants:	

12. 12. Pharmacy

#	Question	Answer
12.1	Will services provided by Pharmacy be required for the study? If no, please skip this tab.	
12.2	Do you require assistance from a Pharmacist for the conduct of your study?	
12.3	Please include a copy of the pharmacy manual in the attachments section. The pharmacy manual should include specific requirements with respect to the investigational product. Information in this manual may include (but not limited to) the following:	
12.4	If no, please explain.	
12.5	Will pharmacy be involved in the randomization process?	
12.6	If yes, please include details on the procedure.	
12.7	Will there be an on-site initiation visit?	
12.8	Will an Island Health Pharmacy administer the drug?	
12.9	If no, who will administer the drug? Eg principal investigator, research coordinator, external pharmacy.	
12.10	Will a drug (investigational or marketed drug) be stored by Island Health Pharmacy?	
12.11	If yes, the Island Health Pharmacy must review the research project protocol and provide operational approval.	
12.12	Please list the study coordinator, name, email and telephone number:	
12.13	Please name the Research Agency.	
12.14	Please list the mailing address and/or the email address to send the billing invoices.	
12.15	How long is this study anticipated to be active?	
12.16	Are the participants:	
12.17	What dispensing activities are required?	
12.18	What dose preparation services are required? (eg compounding)	
12.19	Please list all Island Health Sites involved in the conduct of your study:	

12.20	Please provide the names of the Prinicipal Investigator and sub-investigators at each hospital site:	
12.21	Please list populations:	
12.22	Please indicate study design. (eg double blind clinical trial)	
12.23	If the study is blinded to everyone except pharmacy, please include the un-blinded investigator contact information.	

13. 13. Study Procedures and Assessments

#	Question	Answer
13.1	Will research participant recruitment occur on a hospital ward/clinic/community site? Or will any research project visits/assessments take place on a hospital ward/clinic/community site?	
13.2	If yes, an approval from the patient service department of each hospital ward/clinic/community site must be obtained.	
13.3	If approvals are not uploaded, please explain:	
13.4	Where will informed consent be obtained?	
13.5	If a questionnaire will be administered where will this occur?	
13.6	If a focus group will be held or interview conducted, where will this occur?	
13.7	Island Health employees – will the questionnaire of focus group be held within Island Health working hours?	

14. 14. Medical Device Reprocessing/Biomedical Engine ...

#	Question	Answer
14.1	As part of your project will you be using any device which contacts the patient directly or is used within the sterile field?If no device involved in the study, please skip to the next tab.	
14.2	If yes, will the device be expose to a sterile cavity (e.g. critical device) or mucous membrane or non-intact skin (e.g. a semi-critical device)?	

14.3	If no, the device is considered a non-critical device. To ensure infection control safety between patients a plan with instructions for cleaning and disinfection between patients uses need to be provided. Please contact the Island Health Research Administrative Coordinator at ResearchOperations@islandhealth.ca for access to Island Health BioMedical Engineering Department.	

15. 15. Recruitment of Research Participants; Recruitm ...

#	Question	Answer
15.1	Do you require any support from Island Health, Research and Capacity Building or the Island Health Internal Weekly Newsletter in the recruitment or advertising of your study? If no, please skip to the next tab.	
15.2	Are you ONLY requesting to post an advertisement or recruitment material?	
15.3	Will any notices for recruitment be posted in a hospital ward/clinic/community site?	
15.4	Will any notices for recruitment be posted in any public/common areas of Island Health? (eg elevators, cafeteria, doors, bulletin boards)?	
15.5	Will study information be sent via email by Island Health for recruitment purposes (Island Health broadcast email)?	
15.6	Would you like the Island Health Communications Department to promote your research project on Twitter @VIHealthRes?	
15.7	If the Researcher and Team feel that this trial should not be posted on the Island Health website, please explain why:	
15.8	Island Health Email Distribution and/or the Weekly Newsletter:	
15.9	Headline:	
15.10	Short Description:	
15.11	Body of the Article:	
15.12	Notes for the Editor:	
15.13	Publish Date:	
15.14	Disable Comments:	

15.15	Please attach documents, posters or images to this application.	
15.16	In 75 words or less, please describe purpose of the study:	
15.17	Who can participate?	
15.18	In 75 words or less what is involved in your study?	

16. If you have any questions related to this form, please contact Julita Traylen, Research Administrative Coordinator, Operational Review and Approvals, 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.

Please remember to attach your latest RISe application, study protocol and consent form.

You are asked to review the latest guidance before finalizing and submitting an new research ethics applications, amendments or annual renewal and other ongoing review activities:

https://www.islandhealth.ca/research-capacity-building/research-ethics-compliance-office/operational-review-institutional-approval