

## APPLICATION GUIDANCE & INSTRUCTIONS

Institutional approval is required for all studies and must be issued before you start your research project.

Ethics Approval + Operational Approval = Institutional Approval

Each department or program will determine whether they are able to support the research.

### Seek consultations early and often

Do you have a research idea, but aren't sure where to start? We have your research roadmap! Contact our Research Facilitation Team, [ResearchFacilitation@islandhealth.ca](mailto:ResearchFacilitation@islandhealth.ca)

|                         |   |
|-------------------------|---|
| Clinical Trials Unit    | <a href="mailto:ClinicalResearch@islandhealth.ca">ClinicalResearch@islandhealth.ca</a> or 250.370.8111 x13511     |
| Compliance and Training | <a href="mailto:ResearchCompliance@islandhealth.ca">ResearchCompliance@islandhealth.ca</a> or 250-519-5300 x36220 |
| Contracts/Agreements    | <a href="mailto:ResearchandSupportServices@islandhealth.ca">ResearchandSupportServices@islandhealth.ca</a>        |
| Data Access             | <a href="mailto&gt;DataDevelopment@islandhealth.ca">DataDevelopment@islandhealth.ca</a>                           |
| Privacy Specialist      | <a href="mailto:ResearchPrivacy@islandhealth.ca">ResearchPrivacy@islandhealth.ca</a>                              |

### Island Health Operational Review & Institutional Approval eLearning Course

This course guides researchers—especially those new to institutional review—through the process of submitting an operational application, meeting Island Health's requirements, and obtaining Institutional Approval (IA). (Launched May 2024)

[Register Here](#)

**Please read these instructions before you begin.**

Submit this application form for operational review along with your ethics application. Ethics review and operational review are two separate review processes conducted concurrently

1) **FILL OUT FORMS COMPLETELY.** Each section is assessed by different departments or programs, and each reviewer may focus on specific aspects of your application. Providing all requested information, even if it's similar to what was included in another form or document, ensures that all reviewers have the complete and consistent information they need to assess your application thoroughly.

- Applications will undergo a review for completeness before being assigned for review.
- If your application is not complete, it will be sent back via a "Request for Information" email.
- Check the **Errors** tab: When all Application Form requirements are met, the Error tab disappears, and the PI is able to submit the Application Form.

#### 2) Project Team - List ALL Members

- List all members who must appear on your Institutional Approval certificate.
- If a team member does not have an account, ask them to register. Alternatively, list all members in the "Comments" section of the PI's profile. Include their title/role, affiliation/employer.
- If this is incomplete, your application will be sent back to you.

#### 3) Below is a [document checklist](#) you should use to make sure you have all required materials for submission:

1. A PDF of your current RISE application (if a multi-jurisdictional study) \*required\*
2. Study protocol / proposal \*required\*
3. Consent form \*required, if applicable\*
4. Department supports documents if obtained
5. Data flow diagram or Data Management Plan

#### READY TO SUBMIT YOUR OPERATIONAL APPLICATION? Have you

- Provided all required information
- Added Team members to the Project Team
- Uploaded required documents.

#### WHO CAN SUBMIT THE APPLICATION FORM?

Application Form submission permissions are restricted to the Principal Investigator role.

#### YOUR APPLICATION WILL BE ASSIGNED FOR REVIEW

You will be cc'd on a "Request for Review" email to Reviewers, for your records.

#### TRACK THE STATUS OF YOUR OPERATIONAL APPLICATION

- ROMEO will show you the status as Pending or Approved
- For additional information, email [ResearchOperations@islandhealth.ca](mailto:ResearchOperations@islandhealth.ca) and quote your ROMEO file # and study number.

#### [Quick Guide to Applying for Operational Review at Island Health](#)

#### Is your study's only connection to Island Health via Team Member Affiliation?

You will need to submit an operational application and receive an Institutional Approval. Please contact [ResearchOperations@islandhealth.ca](mailto:ResearchOperations@islandhealth.ca) for further guidance on how to complete the operational application for Team Member Affiliation only.

#### Recruitment support for External Researchers

For Researchers who are external to Island Health or Research Ethics BC (your study is not harmonized in RISE/PREP). If you are a researcher whose:

- study has been approved by an external REB
- you are requesting [recruitment support only](#)
- you are not requesting any services from Island Health

Please follow these steps:

- 1) Email [ResearchEthics@islandhealth.ca](mailto:ResearchEthics@islandhealth.ca)
  - 2) Include "External researcher seeking recruitment support" in the subject line.
  - 3) Attach your REB Certificate of Approval and copy of material(s) to be distributed.
- The Research Ethics & Compliance Manager will review and respond to your request.

#### Is it Quality Improvement or Research?

If you are unsure, please complete the Island Health Quality Improvement (QI) Ethics Decision Making Tool and Registry and a consultant will review to determine if it's QI or requires REB Review.

[QI Ethics Decision-Making Tool](#)

For more on our Operational Review & Institutional Approval process, visit <https://www.islandhealth.ca/research-capacity-building/research-ethics-compliance-office/operational-review-institutional-approval>

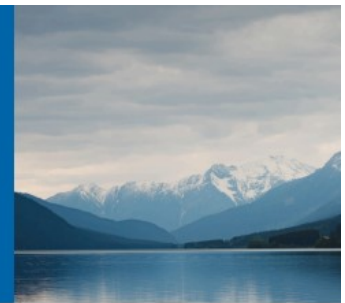
#### Application Technical Support

|                         |  |
|-------------------------|--|
| ROMEO Tech Support      | <a href="mailto:ResearchEthics@islandhealth.ca">ResearchEthics@islandhealth.ca</a>         |
| Ethics Application      | <a href="mailto:ResearchEthics@islandhealth.ca">ResearchEthics@islandhealth.ca</a>         |
| Operational Application | <a href="mailto:ResearchOperations@islandhealth.ca">ResearchOperations@islandhealth.ca</a> |



# How to Apply for Research Operational Review

OPERATIONAL APPROVAL IS REQUIRED FROM THE DEPARTMENT OR PROGRAM DIRECTORS, DELEGATES AND/OR MANAGERS BEFORE INSTITUTIONAL APPROVAL CAN BE GRANTED FOR ANY RESEARCH PROJECT



## Guide for Applicants



### 1. Log in to the [Research Services Portal](#)

### 2. Apply New - Select the Operational Application

V24 Operational Review to Conduct a Research Project at Island Health

### 3. Read Instructions First

Tab 1. Instructions START HERE

### 4. Project Team Info

Provide the names of all study team members in the Project Team section.

List team members who must appear on the Institutional Approval certificate.

### 5. Upload Documents

- RISE application (PDF)
- Study protocol
- Consent form(s)
- Other (department, program or academic supports, data flow diagram)

### 6. Clearly Define Your Asks for Our Reviewers

**This is not a duplicate of your ethics application**

Department and Program Directors and Managers will review your application and assess the impact on their time, sites, people, resources, data. Privacy and Contracts may also review. **Clearly defined asks will allow the reviewers to conduct an informed review and provide approval efficiently.**

### 7. Check the **Errors** tab

If all required questions are complete you can submit.

### 8. Submit

**Incomplete forms** will be sent back via a Request for Information email

**Complete forms** will be processed by our office and assigned to departments and programs for review and approval

**Expect the operational review process to take approx 6 weeks**

### Island Health Research Services Portal



To register for an account, email

[ResearchEthics@islandhealth.ca](mailto:ResearchEthics@islandhealth.ca)

#### Provide

First & Last Name

Institutional Email Address (Gmail, Hotmail, etc not permitted)

Primary Institution Affiliation

Work Telephone Number

Main Work Location (if hospital)

An email confirmation and password reset link will follow.

#### Forgot your password?

To reset your password, visit

<https://viha.researchservicesoffice.com/Romeo.Researcher> and click on the Reset Password button



### Who can submit the application?

The PI can designate a study team member to be the administrator of the operational application. The designate can enter the info, edit and submit the operational application on the PI's behalf.



### Approval

Once operational review is complete and the Certificate of Ethical Approval (CoA) is released, you will receive an Institutional Approval certificate (IA)

### Post Approval

When you approach a department or program for a service, provide a copy of your CoA, IA and the IA email listing approvers.



# SAMPLE FORM

## V24 Operational Review to Conduct a Research Project at Island Health

### 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 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:**

Instructions : Do not hand type data for this section.  
 The Principal Investigator (PI) section default populates with the researcher profile data for the project team member who creates the file. If you are not the PI, click the Change PI button to search for and select an alternate researcher profile.  
 If you load an alternate researcher profile to the PI section, be sure to reload your researcher profile to the Other Project Team Info section below.

### Common Questions

## 1. 1. Instructions START HERE

## 2. 2. Project Information

| #    | Question   | Answer   |
|------|--|--|
| 2.1  | Research Project Title:  | Please provide the full study title and the short title.   |
| 2.2  | REB or RISE Study File Number:   |  |
| 2.3  | Harmonized Board of Record:  | If your study is harmonized in RISE, please list the board of record (eg. Island Health, C&W, UBC)   |
| 2.4  | Island Health Collaborator: Name, Address, Telephone and Email.  | An Island Health Collaborator is not mandatory, but it is an asset. If you need help finding a collaborator, please connect to the Research Facilitator via <a href="mailto:ResearchFacilitation@islandhealth.ca">ResearchFacilitation@islandhealth.ca</a> |
| 2.5  | Primary Contact Person: Name, Address, Phone and Email.  |  |
| 2.6  | Study Summary--Summarize the research proposal for our operational reviewers--Clearly define what Island Health resources and services you want access to. Include: Purpose, Hypothesis, Justification, Objectives, Research Design, and Statistical Analysis.           | Do not mark with 'as per protocol' or 'please see protocol'. Please note that operational reviewers require a breakdown of the study protocol. Clearly define what Island Health resources or services you want access to.                                 |
| 2.7  | 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.  |  |
| 2.8  | How many participants (including controls) will be enrolled at the institutions covered by this Research Ethics Approval?  | Please avoid a range of participants -- an estimate of the number of participants required so our staff can plan accordingly.  |
| 2.9  | 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:  |  |
| 2.10 | If Island Health staff/physicians will be involved in the recruitment of participants for the study, please describe what the involvement will entail.   | Each department/program has a director who will review your application to determine the impact on their staff time and dept resources. For an efficient review, clearly define what you are asking for from the department or program director.           |
| 2.11 | 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.   | Make sure you've considered all the resources needed at all sites.   |
| 2.12 | Please identify all departments or programs where personnel will be requested to support the study. If the department or program director name is known, please provide it here. If department or program name is unknown, please identify the type of support required. |  |
| 2.13 | Type of Study:   | If you check Anonymous Survey please note: the research study is only a survey, there no way to directly identify who has completed the survey.  |
| 2.14 | 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:  | Please list name of the Island Health clinical unit, other resources, or Island Health database  |
| 4.3 | Please describe any additional information not found in the list of departments that you require access to at Island Health: | List department or program not included in question 4.3 here. Island Health Services and Departments <a href="https://www.islandhealth.ca/our-services">https://www.islandhealth.ca/our-services</a> |
| 4.4 | Please attach the Departmental Cost Analysis or Cost and Support Letter from each department impacted by your research:      | While prepping your application for Ethics review, if you contact any of the Island Health Departments for support please upload approvals to the attachments tab.                                   |

#### 5. 5. Health Information Management (Health Records)

| #    | Question  | Answer   |
|------|---|--|
| 5.1  | Does this study require access to Island Health Health Records? Either electronic health record, paper charts or outpatient clinic records? If 'no', please skip to next tab.               | Please note, even if you are an Island Health Employee with access to records, you must indicate if you require access as a researcher.  |
| 5.2  | Will any non-Island Health study team members* review medical records? Please confirm.  | *for example, study sponsor in a clinical trial.   |
| 5.3  | Please provide the full name(s) of the person(s) responsible for retrieving the records. Ensure that each individual is listed in the Project Team Information section of this application. |  |
| 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 | Please specify the location of the patient records, including the clinic name, ward, department, or community site. If the location is unknown, please write 'unknown.'                     | Island Health Information Stewards review and approve requests for access to data and health records. The Information Stewards list is limited to Information Stewards whose data is loaded into the Enterprise Data Warehouse (EDW). For other areas we will need to identify the steward responsible and find their contact details. |
| 5.12 | Who will be pulling the charts and providing them to the researchers:   |  |
| 5.13 | Is this a retrospective 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 | Chart Requests Post Institutional Approval: You will need to provide the name of the study, a copy of the Island Health Institutional Approval (IA), a copy of the Certificate of Ethical Approval (CoA), a copy of the email listing approved departments, 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 for advice or data provision? Do you need access to an Island Health database? (Yes or No)  | If you answered "Yes," please proceed to complete the remaining questions below. The information you provide is necessary for the Decision Support Consultants to review your application. If additional clarification is needed, a consultant will contact you for further details. |
| 6.2  | Have you applied for access to the Health Data Platform BC (HDPBC)?   | The HDPBC may be a further source of data pertinent to your study. For more info, speak with Decision Support.   |
| 6.3  | Have you already had a consultation with someone from Decision Support? (Yes or No)   |  |
| 6.4  | If yes, who did you consult with? Please provide their name.  |  |
| 6.5  | For retrospective studies and chart access, how will the patient population of interest be identified?  |  |
| 6.6  | Briefly describe the type of data that you intend to collect (eg. disease, diagnosis, outcome, demographic, aggregate, personal-level)  |  |
| 6.7  | Are you collecting and retaining personally identifiable information to be a part of the data set?  |  |
| 6.8  | 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.   |  |
| 6.9  | 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.  |  |
| 6.10 | Please explain how the researcher will take appropriate measures to protect the privacy of individuals and to safeguard the identifiable information.   |  |
| 6.11 | Please explain how the researchers will comply with any known preferences previously expressed by individuals about any use of their information.   |  |
| 6.12 | Please explain why it is impossible or impracticable to seek consent from individuals to whom the information relates.  |  |
| 6.13 | Please describe how the researchers will obtain any other necessary permissions for secondary use of the information for research purposes.   |  |
| 6.14 | 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.   |  |
| 6.15 | 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. |  |

|      |   |  |
|------|---|--|
| 6.16 | 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. |  |
| 6.17 | 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 | Approvals from the applicable data steward(s) aka information steward(s) is required and are obtained via this operational review process. If you have already obtained approvals from the applicable stewards, please upload to the Attachments tab.   |  |

**7. 7. Privacy and Agreements** Information Stewardship, Audit, and Privacy (ISAP): A Privacy Specialist may be assigned to review your operational application. The Privacy Reviewer will reach out to you directly with follow-up questions if clarification is needed or to issue changes.

| #    | Question   | Answer  |
|------|--|---|
| 7.1  | Will non-Island Health personnel need access to Island Health facilities, services, systems or data for a study component? (Yes or No)   |   |
| 7.2  | If yes, please enter a brief description.  |   |
| 7.3  | If yes, what system(s) do you want access to, please list/describe.  |   |
| 7.4  | Provide name and email address of study team members who will have access to the system(s):  |   |
| 7.5  | Are any members of your study team Island Health employees? e.g. Physicians, employees, contractors. If yes, please review Guidance for Clinical Research Training Requirements (Yes or No)  | <a href="https://www.islandhealth.ca/research-capacity-building/research-ethics-compliance-office/res">https://www.islandhealth.ca/research-capacity-building/research-ethics-compliance-office/res</a> |
| 7.6  | Is data being transferred outside of Island Health? (Yes or No)  |   |
| 7.7  | If yes, where is data being transferred to? Provide institution or agency name, and contact details.   | Data transfer details are reviewed by Decision Support, Privacy and Contracts/Agreements.   |
| 7.8  | If yes, how does the data move from one place to another? Please explain how the data moves through the stages of collection, use, storage, processing, sharing and disposal. If you have a data flow diagram, upload it to the Attachments tab. |   |
| 7.9  | Are you requesting data to leave Island Health without participant consent? (Yes or No) For example will Island Health provide a data extract which will be stored at another organization by the research team?                                 |   |
| 7.10 | If yes, please describe:   |   |
| 7.11 | Are you implementing any new systems hardware, software, or infrastructure at Island Health to support your research? e.g. registries, biobanks, apps (Yes or No)  |   |

|      |   |   |
|------|---|---|
| 7.12 | Is data collection occurring? (Yes or No)   |   |
| 7.13 | If yes, describe how data (personal information) will be de-identified or aggregated.   |   |
| 7.14 | Which tools are you using for data analysis? Please list:   |   |
| 7.15 | What outputs do you intend to transfer out of Island Health? Please describe.   |   |
| 7.16 | If you anticipate that small cell size will be an issue for your project*, please describe measures that will be taken to protect against risk of possible re-identification in any publication or distribution of results. |   |
| 7.17 | Where will data outputs be stored? Please describe storage:   | Please note: the use of a personal laptop is not sufficient for privacy purposes. |
| 7.18 | Will contact information of patients be extracted from an Island Health data source and used for recruitment purposes? (Yes or No)  |   |
| 7.19 | If yes, have the patients consented to being contacted for future research? (Yes or No)   |   |
| 7.20 | If yes, where will consent be obtained?   |   |
| 7.21 | Have any potential privacy risks been identified in the study? If yes, please describe.   |   |
| 7.22 | Are human samples being transferred out of Island Health? (Yes or No)   |   |
| 7.23 | If yes, where are samples being transferred to? Provide Agency name and contact details.  |   |
| 7.24 | Are you conducting interviews either in person, virtually, or both?   |   |
| 7.25 | If yes, you are conducting interviews, please explain 1) how the interview will be recorded and transcribed (ie which tools or software will be used) and 2) how recordings will be stored and/or transferred.              |   |

## 8. 8. Laboratory Medicine

| #    | Question   | Answer |
|------|--|--------|
| 8.1  | Are Laboratory Services provided by Island Health required for this study? If no, please skip to the next tab.             |        |
| 8.2  | Please enter the name phone number and email address of the study coordinator:   |        |
| 8.3  | Submit billing invoice to: (name, address, email address) if different from above.   |        |
| 8.4  | Please ensure a copy of the lab manual for the study is included in the attachments tab.                                   |        |
| 8.5  | If no, please explain.   |        |
| 8.6  | Number of participants that require lab:   |        |
| 8.7  | Number of lab collections per study participant:   |        |
| 8.8  | Are the participants:  |        |
| 8.9  | Specimen types:  |        |
| 8.10 | If other specimen type, please describe.   |        |
| 8.11 | Is local analysis required?  |        |
| 8.12 | Please list the tests to be performed by local Island Health lab, (only list above standard of care)                       |        |
| 8.13 | Are any test required on a STAT basis?   |        |
| 8.14 | If yes, please name the test.  |        |
| 8.15 | If samples are to be sent to another lab for analysis, please identify who will be responsible for packaging and shipping: |        |



|      |   |  |
|------|---|--|
| 8.16 | Please describe the shipping requirements for the other lab:                        |  |
| 8.17 | Name and address of other lab (if applicable):                                      |  |
| 8.18 | If shipping to be done by Island Health lab, who will provide the shipping supplies |  |
| 8.19 | If a specific courier service is required, please provide details:                  |  |

## 9. 9. Medical Imaging

\*Please do not fill this out for Heart Health images eg. ECG and echocardiogram diagnostics. Those requests should be completed under the Heart Health Tab - Tab #10.

| #    | Question   | Answer |
|------|--|--------|
| 9.1  | Are Medical Imaging services required for this study?<br>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 and address if different from above):  |        |
| 9.4  | Attach any manuals or study specific documents pertaining to Medical Imaging requirements under the attachments tab. |        |
| 9.5  | If not attached, please explain:   |        |
| 9.6  | Number of participants that will require Medical Imaging:  |        |
| 9.7  | Number of exams/scans per participant or attach a schedule of events under the attachments tab.                      |        |
| 9.8  | Are the participants:  |        |
| 9.9  | Modality types:  |        |
| 9.10 | Please describe the type of exam and if contrast is required.  |        |
| 9.11 | Will results have:   |        |
| 9.12 | Please list above standard-of-care exams required:   |        |
| 9.13 | Are any exams required on a STAT basis?  |        |
| 9.14 | If yes, please specify exam name:  |        |
| 9.15 | Are tumor measurements required for every CT scan? (where applicable)  |        |
| 9.16 | How are tumor measurements required to be performed? Eg RECIST 1.1   |        |
| 9.17 | Is a Bone Scan Assessment Worksheet required?  |        |
| 9.18 | If yes, please include this in the attachments tab.  |        |
| 9.19 | If no, please explain.   |        |
| 9.20 | Please describe your proposed process to send images.  |        |

## 10. 10. Heart Health

| #    | Question  | Answer |
|------|---|--------|
| 10.1 | Will services provided by Heart Health unit be required for the study? If no, please skip this tab. |        |
| 10.2 | Please enter the name, phone number and email address of the Study Coordinator:                     |        |
| 10.3 | Submit billing invoice (name and address) if different from above.                                  |        |
| 10.4 | Please indicate the number of participants:   |        |
| 10.5 | Number of exams per participant or attach a schedule of events:                                     |        |
| 10.6 | Are the participants:   |        |

## 11. 11. Pharmacy

| # | Question | Answer |
|---|----------|--------|
|---|----------|--------|

|       |   |   |
|-------|---|---|
| 11.1  | Will services provided by Pharmacy be required for the study? If no, please skip this tab.  |   |
| 11.2  | Do you know if this research project involves the services of Pharmacy Informatics for advice or data provision?  |   |
| 11.3  | Do you require assistance from a Pharmacist for the conduct of your study?  |   |
| 11.4  | Pharmacy Manual 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: | The pharmacy manual should include specific requirements with respect to the investigational product. |
| 11.5  | If no, please explain.  |   |
| 11.6  | Will pharmacy be involved in the randomization process?   |   |
| 11.7  | If yes, please include details on the procedure.  |   |
| 11.8  | Will there be an on-site initiation visit?  |   |
| 11.9  | Will an Island Health Pharmacy administer the drug?   |   |
| 11.10 | If no, who will administer the drug? Eg principal investigator, research coordinator, external pharmacy.  |   |
| 11.11 | Will a drug (investigational or marketed drug) be stored by Island Health Pharmacy?   |   |
| 11.12 | If yes, the Island Health Pharmacy must review the research project protocol and provide operational approval.  |   |
| 11.13 | Please list the study coordinator, name, email and telephone number:  |   |
| 11.14 | Please name the Research Agency.  |   |
| 11.15 | Please list the mailing address and/or the email address to send the billing invoices.  |   |
| 11.16 | How long is this study anticipated to be active?  |   |
| 11.17 | Are the participants:   |   |
| 11.18 | What dispensing activities are required?  |   |
| 11.19 | What dose preparation services are required? (eg compounding)   |   |
| 11.20 | Please list all Island Health Sites involved in the conduct of your study:  |   |
| 11.21 | Please provide the names of the Principal Investigator and sub-investigators at each hospital site:   |   |
| 11.22 | Please list populations:  |   |
| 11.23 | Please indicate study design. (eg double blind clinical trial)  |   |
| 11.24 | If the study is blinded to everyone except pharmacy, please include the un-blinded investigator contact information.  |   |

## 12. 12. Study Procedures and Assessments

| #    | Question   | Answer |
|------|--|--------|
| 12.1 | 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?                     |        |
| 12.2 | Approvals will be obtained via this operational review process. If you have obtained support letters independently, or prior to submitting this operational application, please upload to the Attachments tab. |        |

|      |  |  |
|------|--|--|
| 12.3 | If a questionnaire will be administered where will this occur?   |  |
| 12.4 | If a focus group will be held or interview conducted, where will this occur? On site or virtually? Please list sites or describe tools for virtual interviews. |  |
| 12.5 | Will Island Health employees be expected to complete a questionnaire or attend a focus group within Island Health working hours?                               |  |

### 13. 13. Medical Device Reprocessing/Biomedical Engine ...

| #    | Question   | Answer |
|------|--|--------|
| 13.1 | 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.   |        |
| 13.2 | 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)?  |        |
| 13.3 | 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. |        |

### 14. 14. Recruitment of Research Participants; Recruitm ...

| #     | Question  | Answer   |
|-------|---|--|
| 14.1  | Do you require any support from Island Health, Research Department or the Island Health Internal Weekly Newsletter in the recruitment or advertising of your study? If no, please skip to the next tab. | Please note that not all sites or areas within hospitals/clinics permit posting of printed flyers, posters, pamphlets, etc. We review on a case-by-case basis. Further info provided in 14.3 below                                 |
| 14.2  | Are you ONLY requesting to post an advertisement or recruitment material?   |  |
| 14.3  | Will any notices for recruitment be posted in a hospital ward/clinic/community site?  | Signage and Other Posted Materials at Island Health<br><a href="https://www.islandhealth.ca/sites/default/files/2018-08/signage-guidelines.pdf">https://www.islandhealth.ca/sites/default/files/2018-08/signage-guidelines.pdf</a> |
| 14.4  | Will any notices for recruitment be posted in any public/common areas of Island Health? (eg elevators, cafeteria, doors, bulletin boards)?  |  |
| 14.5  | Will study information be sent via email by Island Health for recruitment purposes (Island Health broadcast email)?   |  |
| 14.6  | Would you like the Island Health Communications Department to promote your research project on Twitter @VIHealthRes?  |  |
| 14.7  | If the Researcher and Team feel that this trial should not be posted on the Island Health website, please explain why:  |  |
| 14.8  | Island Health Email Distribution and/or the Weekly Newsletter:  |  |
| 14.9  | Headline:   |  |
| 14.10 | Short Description:  |  |
| 14.11 | Body of the Article:  |  |
| 14.12 | Notes for the Editor:   |  |
| 14.13 | Publish Date:   |  |
| 14.14 | Disable Comments:   |  |
| 14.15 | Please attach documents, posters or images to this application.   |  |

|       |  |  |
|-------|--|--|
| 14.16 | In 75 words or less, please describe purpose of the study: |  |
| 14.17 | Who can participate?                                       |  |
| 14.18 | In 75 words or less what is involved in your study?        |  |

## 15. Questions? And what happens after you submit your...

If you have any questions related to this form, please contact Julita Traylen, Research Administrative Coordinator for Operational Review and Approvals, Island Health at [ResearchOperations@islandhealth.ca](mailto:ResearchOperations@islandhealth.ca)

### For Additional Support Contact:

|                                |  |
|--------------------------------|--|
| Research Facilitation Team     | <a href="mailto:ResearchFacilitation@islandhealth.ca">ResearchFacilitation@islandhealth.ca</a>             |
| Clinical Research Ethics       | CREB Coordinator, <a href="mailto:ResearchEthics@islandhealth.ca">ResearchEthics@islandhealth.ca</a>       |
| Health Research Ethics         | HREB Coordinator, <a href="mailto:ResearchEthics@islandhealth.ca">ResearchEthics@islandhealth.ca</a>       |
| Clinical Trials Unit           | <a href="mailto:ClinicalResearch@islandhealth.ca">ClinicalResearch@islandhealth.ca</a>                     |
| Compliance and Training        | <a href="mailto:ResearchCompliance@islandhealth.ca">ResearchCompliance@islandhealth.ca</a>                 |
| Contracts/Agreements           | <a href="mailto:ResearchandSupportServices@islandhealth.ca">ResearchandSupportServices@islandhealth.ca</a> |
| Decision Support (Data Access) | <a href="mailto:DataDevelopment@islandhealth.ca">DataDevelopment@islandhealth.ca</a>                       |
| Privacy                        | <a href="mailto:ResearchPrivacy@islandhealth.ca">ResearchPrivacy@islandhealth.ca</a>                       |
| ROMEO Tech Support             | <a href="mailto:ResearchEthics@islandhealth.ca">ResearchEthics@islandhealth.ca</a>                         |
| Recruitment Support Digital    | <a href="mailto:IslandHealthResearch@islandhealth.ca">IslandHealthResearch@islandhealth.ca</a>             |

After you Submit your Operational Application for Review

Submission Completeness Screening: The first step is for the reviewing team to check it for completeness.

If Your Application is Incomplete:

You'll receive a "Request for Information" email, a checklist outlining what's missing, and instructions for re-submission.

If Your Application is Complete

- The application is assigned to relevant reviewers, Privacy and Contracts (if applicable).
- You'll receive a copy of a "Request for Review" email, which is for your records, but you don't need to take any further action.



