

Operational Review to Conduct a Research Project at Island Health

Each Clinical Research Ethics and Health Research Ethics Application MUST have an Operational Application submitted at the time of the Ethics Application. Delays in submission of the Operational Application will lead to delays in the Institutional Approval Certificate.

Please use our guidance document to complete this application. To access the guidance document or if you have an questions regarding the content of this application please email ResearchEthics@islandhealth.ca

Please note: Use the attachments tab in this application to upload your study protocol, main consent form and any departmental supports you have already received.

For Additional Support:

Operational Review/Institutional Approval – Research Administrative Coordinator

Kimberly.Horie@islandhealth.ca or 250.519.6726

Clinical Research Ethics – Clinical Research Ethics Board Coordinator Karen.Medler@islandhealth.ca
or 250.519.5300 x 36207

Clinical Trials Unit – Sheilah.Frost@islandhealth.ca or 250.370.8111 x13511

Compliance and Training – Research Compliance Facilitator Tracy.Wong@islandhealth.ca
or 250.370.8111 x36220

Contracts/Agreements – Research Business Manager Dawn.Waterhouse@islandhealth.ca
or 250.370.8764

Data Access – Data Governance Secretariat Brandon.Wagar@islandhealth.ca or 250.519.7700 x 13386

Data Access Request Form: <https://redcap.viha.ca/redcap/surveys/?s=W7PFDT33HM>

Health Research Ethics – Health Research Ethics Board Coordinator Dawn.Pollon@islandhealth.ca
or 250.519.5300 x 36212

Privacy and Security – Simon.Munn@islandhealth.ca or 250.626.2818

Research Facilitator – Amanda.Leddy@islandhealth.ca or 250.370.8261

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 employee/physician/contractor on their team.	
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 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:

2. Project Information

#	Question	Answer
2.1	Research Project Title:	Please Provide the full study title, the short name and the file number if it has been assigned.
2.2	Principal Investigator: Name, Address, Telephone and Email.	Free Text Field
2.3	Principal Investigators Department:	Free Text Field
2.4	Principal Investigator Division:	Free Text Field
2.5	Island Health Collaborator: Name, Address, Telephone and Email.	Free Text Field
2.6	Primary Contact Person: Name, Address, Phone and Email.	Free Text Field
2.7	Name of Funding Source(s):	Free Text Field
2.8	Name of Funding Agency(Agencies):	Free Text Field
2.9	For Funded Studies, please provide name of the institution where the funds will be held:	Free Text Field
2.10	Type of Study:	Evaluation Experimental Health Outcomes Research Focus Group Interview Survey Investigational Drug or Biologic Trial – Study Phase I Investigational Drug or Biologic Trial – Study Phase II Investigational Drug or Biologic Trial – Study Phase III Investigational Drug or Biologic Trial – Study Phase IV Investigational Medical Device Trial Natural Health Product Trial Observational Study Registry Retrospective Chart Review Surgical Trial Other
2.11	If other, please describe:	Free Text Field

3. Study Team Information

#	Question	Answer
3.1	The Principal Investigator on this research project (one of the following must apply, check all that apply):	Has medical appointment with Island Health Is an employee of Island Health Is an Island Health Researcher Is an Island Health Affiliated Investigator Is in the process of applying for an Island Health Affiliated Investigator appointment
3.2	If the Principal Investigator is an Island Health employee, please indicate which professional discipline the Principal Investigator is a member (Check all that apply):	Audiology Clinical Nutrition Diagnostic Imaging Laboratory Musical Therapy Nursing Occupational Therapy Pharmacy Physiotherapy Psychology Recreation Therapy Respiratory Therapy Social Work Speech Language Pathology Spiritual Care Other
3.3	If other, please describe:	Free Text Field

4. Funding Information and Study Type

#	Question	Answer
4.1	Name of Funding Source(s):	Free Text Field
4.2	Name of Funding Agency (or Agencies):	Free Text Field
4.3	For Funded Studies, please provide the name of the institution where the funds will be held:	Free Text Field
4.4	Type of Funding Source:	For Profit Sponsor (Includes pharmaceutical or clinical trial industry or grants from either) Not-For-Profit Grant Internal Funds No Funding Not applicable Other
4.5	If other, please describe:	Free Text Field
4.6	Type of Study:	Evaluation Experimental Health Outcomes Research Focus Group Interview Survey Investigational Drug or Biologic Trial – Study Phase I Investigational Drug or Biologic Trial – Study Phase II Investigational Drug or Biologic Trial – Study Phase III Investigational Drug or Biologic Trial – Study Phase IV Natural Health Product Trial Observational Study Registry Retrospective Chart Review Surgical Trial Other
4.7	If other, please describe:	Free Text Field

5. Poster Approvals

#	Question	Answer
5.1	Are you ONLY requesting to post an advertisement or recruitment material?	Yes No
5.2	Please select the Island Health recruitment support that will be required to conduct this research:	Put up a poster or advertisement within at least one Island Health Location Circulating an e-poster or advertisement by email to Island Health clinics or staff

6. Island Health Departments

#	Question	Answer
6.1	Island Health Departments impacted by this research project.	Aboriginal Health Access and Transitions Ambulatory Care Anesthesia Children, Youth and Families Children, Youth and Families, Mental Health and Substance Use Clinical Operations Clinical Operations – Campbell River Hospital Clinical Operations – Cowichan District Hospital Clinical Operations – Nanaimo Regional General Hospital Clinical Operations – Royal Jubilee Hospital Clinical Operations – Saanich Peninsula Hospital Clinical Operations – Victoria General Hospital Clinical Operations – West Coast General Hospital Clinical Operations – Tofino General Hospital Clinical Trials Unit Communications Community Health Services Contracts/Agreements Data Access Data Steward – Children, Youth and Families, Mental Health and Substance Use Data Steward – COVID Data Steward – Discharge Abstract Database (DAD) Data Steward – Emergency Data Data Steward – Encounters/Vital Stats Data Steward – Enterprise Data Warehouse Data Steward – Financial Data Data Steward – Heart Health Data Steward – Home and Community Care Data Steward – Infection and Prevention Control Data Steward – Laboratory Medicine Data Steward – Mental Health and Substance Use Data Steward – Pharmacy Data Steward – Public and Population Health

		<p>Data Steward – Residential Care (Long Term Care)</p> <p>Data Steward – Royal Jubilee Hospital</p> <p>Data Steward – Surgical Services</p> <p>Data Steward – Timekeeping/Payroll</p> <p>Data Steward – Victoria General Hospital</p> <p>Data Steward – Workforce Optimization</p> <p>End of Life, Palliative Care or Medical Assistance in Dying (MAID)</p> <p>Emergency Operations Centre</p> <p>Emergency/Trauma/ Intensive Care Unit</p> <p>Executive Director Geography I</p> <p>Executive Director Geography II</p> <p>Executive Director Geography III</p> <p>Executive Director Geography IV</p> <p>Family Practice Residents/Island medical Program/Division of Family Practice</p> <p>Food and Nutrition</p> <p>Health Information Management (paper charts)</p> <p>Health Information Management (PowerChart)</p> <p>Health Information Management (outpatient clinics)</p> <p>Heart Health</p> <p>Innovation and Analytics</p> <p>Laboratory Medicine</p> <p>Laboratory Microbiology</p> <p>Laboratory Pathology</p> <p>Medical Daycare</p> <p>Medical Imaging</p> <p>Mental Health and Substance Use (Central/North Island)</p> <p>Mental Health and Substance Use (South Island)</p> <p>Neurology</p> <p>Nuclear Medicine</p> <p>Nursing</p> <p>Pharmacy</p> <p>Physiotherapy</p> <p>Privacy – Information Security</p> <p>Public Health</p> <p>Renal Trauma</p> <p>Research and Capacity Building</p> <p>Residential Care Services (Long Term Care)</p> <p>Residents/Hospitalists (Central Island)</p> <p>Residents/Hospitalists (South Island)</p>
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		Respiratory Seniors/Tertiary Mental Health SIM Lab Surgical Services Victoria Hospice Volunteer Services
6.2	Island Health database (PACS, ORMIS) or other, please describe:	Name of Clinical Unit, Other Resources, or Database
6.3	Please describe any additional information not found in the list of departments that you require access to at Island Health:	Free Text Field
6.4	Please attach the Departmental Cost Analysis or Cost and Support Letter from each department impacted by your research:	Yes, uploaded to the attachments tab No, not required

7. Study Personnel

#	Question	Answer
7.1	The Principal Investigator on this research project (one of the following must apply, check all that apply):	Has a medical appointment within Island Health Is an employee of Island Health Is an Island Health Researcher Is an Island Health Affiliated Investigator Is in the process of applying or an Island Health Affiliated Investigator appointment
7.2	If the Principal Investigator is an Island Health employee, please indicate which professional discipline the Principal Investigator is a member, check all that apply:	Audiology Clinical Nutrition Diagnostic Imaging Laboratory Medicine Music Therapy Nursing Occupational Therapy Pharmacy Physiotherapy Psychology Recreation Therapy Respiratory Therapy Social Work Speech Language Pathology Spiritual Care Other
7.3	If other, please describe:	Free Text Field
7.4	Study Participants and Access to Personal Information: Study participants include:	Inpatients Outpatients Long Term Care Residents Island Health Staff Chart Review Other
7.5	If other, please describe:	Free Text Field
7.6	Anticipated total number of study participants	Free Text Field
7.7	Will you or any of your research team member's access identifiable personal information of Island Health patients, clients, residents, and/or staff in this research project? Please describe:	Free Text Field

8. Health Records, Decision Support and Databases

#	Question	Answer
8.1	Does this study require access to Health Records (either electronic health record, paper charts or outpatient clinic records)?	Yes No
8.2	Confirm that any medical records that require review by a non-Island Health study team member (study sponsor in a clinical trial for example):	Confirmed N/A
8.3	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:	Yes No
8.4	Please enter the name, phone number and email address for the Study Coordinator:	Free Text Field
8.5	Please submit billing invoice to (name and address) if different from above:	Free Text Field
8.6	Please select the most accurate statement regarding your study:	This is an unfunded study or academic study All Health Records requests for study purposes will be reimbursed upon invoice from the Health Information Management Department
8.7	Anticipated data collection start date:	Calendar
8.8	Anticipated end date:	Calendar
8.9	Will you require access to patient medical records (charts) located in an Island Health Health Information Management Department?	Yes No
8.10	Number of Health Records required:	Free Text Field
8.11	If known, please advise: where the patient records are located (clinic/ward/department or community site):	Free Text Field
8.12	Who will be pulling the charts and providing them to the researchers:	Free Text Field
8.13	Is this a retrospect chart review study for which participant consent will be obtained?	Yes No Not applicable
8.14	Describe how permission to access the medical records and to collect and use these records will be obtained.	Free Text Field

8.15	Briefly describe the type of data that you intend to collect (eg. disease, diagnosis, outcome, demographic, aggregate, personal-level)	Free Text Field
8.16	Are you collecting and retaining personally identifiable information to be a part of the data set?	Yes No
8.17	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.	Free Text Field
8.18	Please explain if and why the identifiable information is essential to the research.	Free Text Field
8.19	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
8.20	Please explain how the researcher will take appropriate measures to protect the privacy of individuals and to safeguard the identifiable information.	Free Text Field
8.21	Please explain how the researchers will comply with any known preferences previously expressed by individuals about any use of their information.	Free Text Field
8.22	Please explain why it is impossible or impracticable to seek consent from individuals to whom the information relates.	Free Text Field
8.23	Please describe how the researchers will obtain any other necessary permissions for secondary use of the information for research purposes.	Free Text Field
8.24	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.	Free Text Field
8.25	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
8.26	Describe how and where the data will be stored (eg computerized files, hard copy, video recording, audio recording, personal digital device, other).	Free Text Field
8.27	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	Free Text Field Free Text Field

	who will have access to the data in the future and for what purpose.	
8.28	Will data be transferred out of the custody and control of Island Health?	Yes No
8.29	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.	Free Text Field
8.30	Do you plan to link the data to any other data?	Yes No
8.31	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.	Free Text Field
8.32	Will this research project involve the services of Decision Support?	Yes No
8.33	If yes, complete the Island Health Data Access Request https://redcap.viha.ca/redcap/surveys/?s=W7PFDT33HM you must obtain a review from Decision Support	Yes, I have completed the Island Health Data Access Application Form No, I have not completed the Island Health Data Access Application Form
8.34	If you are receiving data from Decision Support will contact information of patients be provided and used for recruitment purposes.	Yes No Not applicable
8.35	Will you require access to data from a database or clinical system in connection with this research project (eg Island Health database such as PACS, ORMIS, PARIS or an internal/department database such as the Orthopedic Trauma Database)?	Yes No
8.36	If yes, please list the databases you will require access to	Free Text Field
8.37	Obtain the approval from the applicable data steward(s).	Yes, I have obtained the approval required and will upload it in the attachments tab No, I have not obtained the approval required
8.38	Will contact information of patients be extracted from an Island Health Data source and used for recruitment purposes.	Yes No
8.39	If yes, have the patients consented to be contacted for future research?	Yes No
8.40	The name of the study, a copy of the Island Health Institutional Approval (including the Certificate of Ethical	Yes, I will comply with the above statement

	<p>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.</p>	
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9. Contracts and Agreements

#	Question	Answer
9.1	Will this study lead to commercialized or a patent issued.	Yes No
9.2	Will there be 3rd party access to Island Health systems or data?	Yes No
9.3	Are Human samples being transferred out of Island Health?	Yes No
9.4	Is this a clinical trial?	Yes No
9.5	Will non-Island Health personnel need to access Island Health facilities/services for a study component?	Yes No
9.6	If yes, please enter a brief description.	Free Text Field
9.7	Do you wish to form a research collaboration with Island Health?	Yes No
9.8	If yes, please describe.	Free Text Field

10. Privacy and Compliance

#	Question	Answer
10.1	Does your study require any member of the study team to access an Island Health system, (such as the Electronic Health Record).	Yes No
10.2	If yes, 1. What system do you want access to, 2. Which study team members will need access to the system(s)?	Free Text Field
10.3	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)	Yes, the Research Privacy Specialist may contact you if further information is required No
10.4	Are you implementing any new systems hardware, software, or infrastructure at Island Health to support your research? (e.g. Registries, biobanks)	Yes, the Research Privacy Specialist may contact you if further information is required No
10.5	Are there Island Health study team members (e.g.. Physicians, employees, contractors)?	If yes, please review Guidance for Clinical Research Training Requirements found on our website

11. Laboratory Medicine

#	Question	Answer
11.1	Are Laboratory Services provided by Island Health required for this study?	Yes If no, please skip to the next tab
11.2	Please enter the name phone number and email address of the study coordinator:	Free Text Field
11.3	Submit billing invoice to: (name, address, email address) if different from above.	Free Text Field
11.4	Please ensure a copy of the lab manual for the study is included in the attachments tab.	Yes, I have attached a copy of the lab manual No, I have not attached a copy of the lab manual
11.5	If no, please explain.	Free Text Field
11.6	Number of participants that require lab:	Free Text Field
11.7	Number of lab collections per study participant:	Free Text Field
11.8	Are the participants:	Inpatient Outpatient
11.9	Specimen types:	Blood Urine Stool Pathology blocks or slides Pathology fresh tissue Microbiology Other
11.10	If other specimen type, please describe.	Free Text Field
11.11	Is local analysis required?	Yes No
11.12	Please list the tests to be performed by local Island Health lab, (only list above standard of care)	Free Text Field
11.13	Are any test required on a STAT basis?	Yes No
11.14	If yes, please name the test.	Free Text Field
11.15	If samples are to be sent to another lab for analysis, please identify who will be responsible for packaging and shipping:	Free Text Field
11.16	Please describe the shipping requirements for the other lab:	Free Text Field

11.17	Name and address of other lab (if applicable):	Free Text Field
11.18	If shipping to be done by Island Health lab, who will provide the shipping supplies	Free Text Field
11.19	If a specific courier service is required, please provide details:	Free Text Field

12. Medical Imaging

#	Question	Answer
12.1	Are medical Imaging services required for this study? If no, please skip to the next tab	Yes If no, skip to the next tab
12.2	Please enter the name, phone number and email address of the study coordinator:	Free Text Field
12.3	Submit billing invoice to (name and address if different from above):	Free Text Field
12.4	Attach any manuals or study specific documents pertaining to medical imaging requirements under the attachments tab.	Yes, manual and study specific documents attached No
12.5	If not attached, please explain:	Free Text Field
12.6	Number of participants that will require medical imaging:	Free Text Field
12.7	Number of exams/scans per participant or attach a schedule of events under the attachments tab.	Free Text Field
12.8	Are the participants:	Inpatient Outpatient
12.9	Modality types:	Breast imaging CT MRI Nuclear medicine Ultrasound Xray
12.10	Please describe the type of exam and if contrast is required.	Free Text Field
12.11	Will results have:	Local review Non-local, central review
12.12	Please list above standard-of-care exams required:	Free Text Field
12.13	Are any exams required on a STAT basis?	Yes No
12.14	If yes, please specify exam name:	Free Text Field
12.15	Are tumor measurements required for every CT scan? (where applicable)	Yes No
12.16	How are tumor measurements required to be performed? Eg RECIST 1.1	Free Text Field

12.17	Is a Bone Scan Assessment Worksheet required?	Yes No
12.18	If yes, please include this in the attachments tab.	Yes, I have included the Bone Scan Assessment Worksheet in the attachments tab No, I have not included the Bone Scan Assessment Worksheet
12.19	If no, please explain.	Free Text Field
12.20	Please describe your proposed process to send images.	Free Text Field

13. Heart Health

#	Question	Answer
13.1	Will services provided by Heart Health unit be required for the study?	Yes If no, please skip to the next tab
13.2	Please enter the name, phone number and email address of the Study Coordinator:	Free Text Field
13.3	Submit billing invoice (name and address) if different from above.	Free Text Field
13.4	Please indicate the number of participants:	Free Text Field
13.5	Number of exams per participant or attach a schedule of events:	Free Text Field
13.6	Are the participants:	Inpatient Outpatient

14. Pharmacy

#	Question	Answer
14.1	Will services provided by Pharmacy be required for the study?	Yes If no, please skip to next tab
14.2	Do you require assistance from a Pharmacist for the conduct of your study?	Yes No
14.3	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:	Yes, I have included the Pharmacy manual in the attachments tab No, I have not attached Pharmacy manual in the attachments tab
14.4	If no, please explain.	Free Text Field
14.5	Will pharmacy be involved in the randomization process?	Yes No
14.6	If yes, please include details on the procedure.	Free Text Field
14.7	Will there be an on-site initiation visit?	Yes No
14.8	Will an Island Health Pharmacy administer the drug?	Yes No
14.9	If no, who will administer the drug? Eg principal investigator, research coordinator, external pharmacy.	Free Text Field
14.10	Will a drug (investigational or marketed drug) be stored by Island Health Pharmacy?	Yes No
14.11	If yes, the Island Health Pharmacy must review the research project protocol and provide operational approval.	Yes, I have attached the approval from the Director of Pharmacy No, I have not attached the approval from the Director of Pharmacy
14.12	Please list the study coordinator, name, email and telephone number:	Free Text Field
14.13	Please name the Research Agency.	Free Text Field
14.14	Please list the mailing address and/or the email address to send the billing invoices.	Free Text Field
14.15	How long is this study anticipated to be active?	Free Text Field
14.16	Are the participants:	Inpatients

		Outpatients
14.17	What dispensing activities are required?	Free Text Field
14.18	What dose preparation services are required? (eg compounding)	Free Text Field
14.19	Please list all Island Health Sites involved in the conduct of your study:	Not Applicable All Sites Campbell River, Comox, Courtney Cowichan Valley North Island Hospital Project Nanaimo Clinical Operations Nanaimo, Oceanside Mt. Waddington, Strathcona Port Alberni, West Coast General Hospital Saanich Peninsula Hospital, Gulf Islands Sooke, Westshore and Esquimalt Victoria, Oak Bay, Royal Oak Victoria Clinical Operations, Royal Jubilee Hospital Victoria Clinical Operations, Victoria General Hospital
14.20	Please provide the names of the Principal Investigator and sub-investigators at each hospital site:	Free Text Field
14.21	Please list populations:	Free Text Field
14.22	Please indicate study design. (eg double blind clinical trial)	Free Text Field
14.23	If the study is blinded to everyone except pharmacy, please include the un-blinded investigator contact information.	Free Text Field

15. Pharmacy Data Stewardship

#	Question	Answer
15.1	Will services/information provided by Pharmacy Data Steward be required for the study?	Yes If no, please skip to the next tab
15.2	Provide details of the data request. What type of medication system is the researcher looking for that is within Pharmacy Information Stewardship?	Free Text Field
15.3	What sources will need to be accessed to provide the data requested (e.g. patient charts, Power-chart, Meds Manager, Cerner Systems)?	Free Text Field
15.4	Has patient provided consent to access medication records?	Yes No
15.5	How will patient confidentiality be maintained for this data extraction?	Free Text Field
15.6	Describe the disposition of this data extract once the study is complete.	Free Text Field

16. Study Procedures and Assessments

#	Question	Answer
16.1	Will research participant recruitment occur on a hospital ward/clinic/community site?	Yes No
16.2	If yes, an approval from the patient service department of each hospital ward/clinic/community site must be obtained.	I have uploaded the approvals to the attachments tab I have not uploaded the approvals to the attachments tab
16.3	If approval are not uploaded, please explain.	Free Text Field
16.4	Where will informed consent be obtained?	Free Text Field
16.5	Will any research project visits/assessment take place on a hospital ward/clinic/community site?	Yes No
16.6	If yes, an approval from the patient service department of each hospital ward/clinic/community site must be obtained.	I have uploaded the approvals to the attachments tab I have not uploaded the approvals to the attachments tab
16.7	If departmental approvals are not uploaded, please explain.	Free Text Field
16.8	If a questionnaire will be administered where will this occur?	Free Text Field
16.9	If a focus group will be held or interview conducted, where will this occur?	Free Text Field
16.10	Island Health employees – will the questionnaire of focus group be held within Island Health working hours?	Yes No
16.11	Will research participants undergo any surgical procedures in the Operating Room?	Yes No
16.12	If yes, an approval from the Operating Room must be obtained on this form.	I have uploaded the approvals to the attachments tab I have not uploaded the approvals to the attachments tab
16.13	If departmental approval is not uploaded, please explain.	Free Text Field
16.14	Indicate which operating room locations will be impacted by the research project.	Free Text Field
16.15	Will tissue specimens be collected from participants in Surgical Services?	Yes No

16.16	Will blood specimens (not standard of care) be collected by anesthesia during a surgical procedure.	Yes No
16.17	Will Island Health Anatomical Pathology process tissue specimens collected in the Operating Room or tissue specimens collected in an Island Health Ward/Clinic/Community Site?	Yes No
16.18	Does this research project involve the utilization of Island Health Anatomical Pathology diagnostic material. (e.g. slides, tissue blocks or tissue procurement?)	Yes No
16.19	If Yes, will the Island Health Laboratory process the samples and report the results?	Free Text Field
16.20	If No, which laboratory will process the samples and report the lab results?	Free Text Field Free Text Field
16.21	Does this study involve the collection of specimens (eg whole blood, serum, plasma, urine, CSF) that will be used for direct patient care?	Yes No

17. Medical Device Reprocessing

#	Question	Answer
17.1	As part of your project will you be using any device which contacts the patient directly or is used within the sterile field?	Yes No
17.2	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)?	Yes 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 ResearchEthics@islandhealth.ca for access to Island Health BioMedical Engineering Department
17.3	If yes:	is it a market device used as intended a device created or modified for the research project
17.4	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 ResearchEthics@islandhealth.ca for access to Island Health BioMedical Engineering Department.	I will contact the Research Administrative Coordinator Not applicable

18. BioMedical Engineering

#	Question	Answer
18.1	Will a medical device (*see guidance document) be involved in the research project? Please check all that apply:	Consumer device Modified consumer device Unlicensed medical device Licensed medical device Modified medical device Research device Accessory device

19. External Resources

#	Question	Answer
19.1	Please advise if any procedures, other than those already mentioned will be performed externally and advise who will be performing the procedure and/or analysis.	Free Text Field

20. Recruitment of Research Participants

#	Question	Answer
20.1	Will any notices for recruitment be posted in a hospital ward/clinic/community site?	Yes No
20.2	Will any notices for recruitment be posted in any public/common areas of Island Health? (eg elevators, cafeteria, doors, bulletin boards)?	Yes No
20.3	Will study information be sent via email by Island Health for recruitment purposes (Island Health broadcast email)?	Yes No
20.4	Would you like the Island Health Communications Department to promote your research project on Twitter @VIHealthRes?	Yes No
20.5	There may be a fee for review of a study poster. If you have any questions please contact the Research Administrative Coordinator at ResearchEthics@islandhealth.ca or 250.519.6726.	I understand and will contact the Research Administrative Coordinator at ResearchEthics@islandhealth.ca
20.6	If the Researcher and Team feel that this trial should not be posted on the Island Health website, please explain why:	Free Text Field
20.7	If the study has not been registered on ClinicalTrials.gov would you like the study information posted on the Island Health Research Website?	Yes, I will complete Appendix A No

21. Appendix A: Recruitment Support Form

#	Question	Answer
21.1	Island Health Website and Email Distribution. Please select one:	<p>Studies registered on ClinicalTrials.gov: Registered studies will be posted on the Island Health website upon receipt of Island Health operational research approval</p> <p>Studies that will not be registered on ClinicalTrials.gov: A researcher may request that Island Health post information on its website about a study that is NOT registered on ClinicalTrials.gov. The study information will be posted on the Island Health website when i) the study receives REB approval and Island Health Operational research approval, and ii) Attachment A receives REB approval.</p>
21.2	Email Distribution	<p>Island Health E-Blast: An Island Health researcher may request that Island Health send information about a study to an Island Health staff distribution list (an "E-Blast"). The E-Blast information will be transferred on to an Island Health template and returned to the researcher for REB approval. The E-Blast will be distributed when i) the study receives REB approval and Island Health Institutional Approval, and ii) the E-blast is approved by the Island REB</p>
21.3	Social Sharing	<p>Please check here if you would like the Island Health Communications Department to promote your research project on Twitter at @VIHealthRes</p> <p>Not applicable</p>
21.4	Recruitment Poster	<p>Please check here if you would like the Island health Communications Department to create a recruitment poster for you. The poster must be submitted to the REB for approval before it can be used for recruitment. There will be a fee for this service</p> <p>Not applicable</p>
21.5	Section 1 ClinicalTrials.gov registration number:	Free Text Field
21.6	Section 2: Check all that apply:	<p>Blood, Heart and Circulation</p> <p>Bones, Joints and Nerves</p>

		Brain and Nerves Digestive System Blood Disorders Ears, Nose and Throat Endocrine System Pregnancy and Reproduction Immune System Kidneys and Urinary System Lungs and Breathing Mouth and Teeth Reproduction System Skin, Hair and Nails Women’s Health Men’s Health Seniors Volunteers (Healthy) Birth Defects Cancer Diabetes Genetics Mental Health and Behaviour Metabolic Problems Eyes and Vision Sleep Smoking Substance Abuse Problems Toxicology and Environmental Health Diagnostic Imaging Surgery and Rehabilitation Rehabilitation Intervention Transplantation and Rehabilitation Food and Nutrition Fitness and Exercise
21.7	Please include three to five additional key words that will help the public to locate this study on the Island Health website:	Free Text Field
21.8	Section 3: Name of study (full title), and the short title or study nickname:	Free Text Field
21.9	In 75 words or less, please describe purpose of the study:	Free Text Field
21.10	Who can participate?	Free Text Field
21.11	In 75 words or less what is involved in your study?	Free Text Field
21.12	Expected Start Date:	Calendar

21.13	Expected End Date:	Calendar
21.14	Where does this study take place, physical location.	Free Text Field
21.15	Principal Investigator, Position, Department and Island Health Affiliation or other Affiliation. (to be noted on the Institutional Approval)	Free Text Field
21.16	Primary Contact Information: name, address, email, phone number	
21.17	Section 4: Please check the appropriate areas for Island Health broadcast recipients:	<p>Geography 1 – Campbell River, Comox, Mr. Waddington-Strathcona</p> <p>Geography 2 – Port Alberni, West Coast, Nanaimo, Oceanside</p> <p>Geography 3 – Cowichan Valley, Saanich and Gulf Islands</p> <p>Geography 4 – Victoria, Saanich, Esquimalt, Sooke, Westshore</p>
21.18	Section 5: REB/RISe File Number and/or Island Health File Number	Free Text Field

22. If you have any questions related to this form, please contact Kimberly Horie, Research Administrative Coordinator, for Operational Review and Approvals, Island Health at Kimberly.Horie@islandhealth.ca or 250.519.6726