Patient Recruitment for Research

25.1.127

PROCEDURE

Procedures are a series of required steps to complete a task, activity or action

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Purpose:	• Outlines the mandatory requirements for all projects recruiting participants for all research conducted at Island Health sites. • Outlines appropriate means of contact under the *Freedom of Information and Protection of Privacy Act* (FIPPA). • To support researchers recruiting patients for Research Ethics Board (REB) and Island Health approved studies, where other options for recruitment may be impractical or unreasonable • To connect patients with research studies that may be of interest to them.
Cultural Safety and Humility:	Island Health offers programs and services on the unceded and traditional territories of the Coast Salish, Nuu-chah-nulth, and Kwakwaka'wakw Peoples. As a signatory to the 2015 Declaration of Commitment to Cultural Safety and Cultural Humility, Island Health is committed to addressing the ongoing impacts of colonialism and Indigenous-specific racism in order to provide a culturally safe, inclusive, healthy and respectful environment. The organization is committed to strengthening diversity, equity and inclusion to enable excellence in health and care for everyone, everywhere, every time. Through these commitments, Island Health strives to deliver the highest possible standard of care and to promote safe workplaces.

Scope:	• **Audience:** All researchers, both Island Health and non-Island Health, who wish to directly contact patients for potential inclusion in research studies.
	• **Environment:**
	  ○ Island Health-wide
	  ○ All care environments
	• **Indications**: All Island Health and non-Island Health research projects, which contemplate direct contact with Island Health patients for potential inclusion in research studies.
	• **Exceptions**: Research projects which already have consent from participants for contact.

Outcomes:	• Personal information of patients is collected, used and disclosed for permitted purposes under FIPPA. • Researchers are able to contact potential participants for research studies using contact information located in Island Health records.

1.0 Background

- Access to research opportunities and the right to participate in research ensures that patients and their families experience the best care at Island Health. Ethical and legal obligations to maintain the confidentiality of patients includes permission from patients to release personal contact information to third-party researchers. As outlined in section 33(3)(h)(ii) of British Columbia's FIPPA, public bodies, such as Island Health (ISLH), are prohibited from disclosing personal information for the purposes of contacting patients to participate in research, unless the individual has either provided consent to be contacted for this purpose or the BC's Information and Privacy Commissioner approves the recruitment strategy.
- The collection of personal information is part of a commitment to provide quality healthcare and services. This data is instrumental in evaluating services, planning effective programs, enhancing patient care experiences, and research as authorized – this information is collected, used and disclosed for these and other permitted purposes under FIPPA (the Permitted Purposes) as reflected on Island Health's Information Notice).

- When recruiting patients for research at Island Health, we *use* information already collected for the Permitted Purposes that is in Island Health's custody, rather than *disclosing* it externally for recruitment purposes. This distinction is crucial under FIPPA, as it determines how privacy obligations are applied. Section 32 (a) permits the *use* of personal information within Island Health for purposes that are consistent with why the information was initially collected. Signage in patient areas informs individuals that information collected during their care may also be used for approved research purposes, which includes contacting the individual about relevant research. Recruiting participants as described in the three methods below, using information already held by Island Health aligns with FIPPA's definition of "use" and does not constitute a section 33 (3)(h)(ii) disclosure.
- With patient care at the core of our mission, we may reach out to patients to invite them to participate in research studies aligned with their medical history or treatments received at our facilities. This invitation is extended respectfully, lawfully and in consideration of patients' interests and privacy preferences.

2.0 Recruitment Approaches Overview

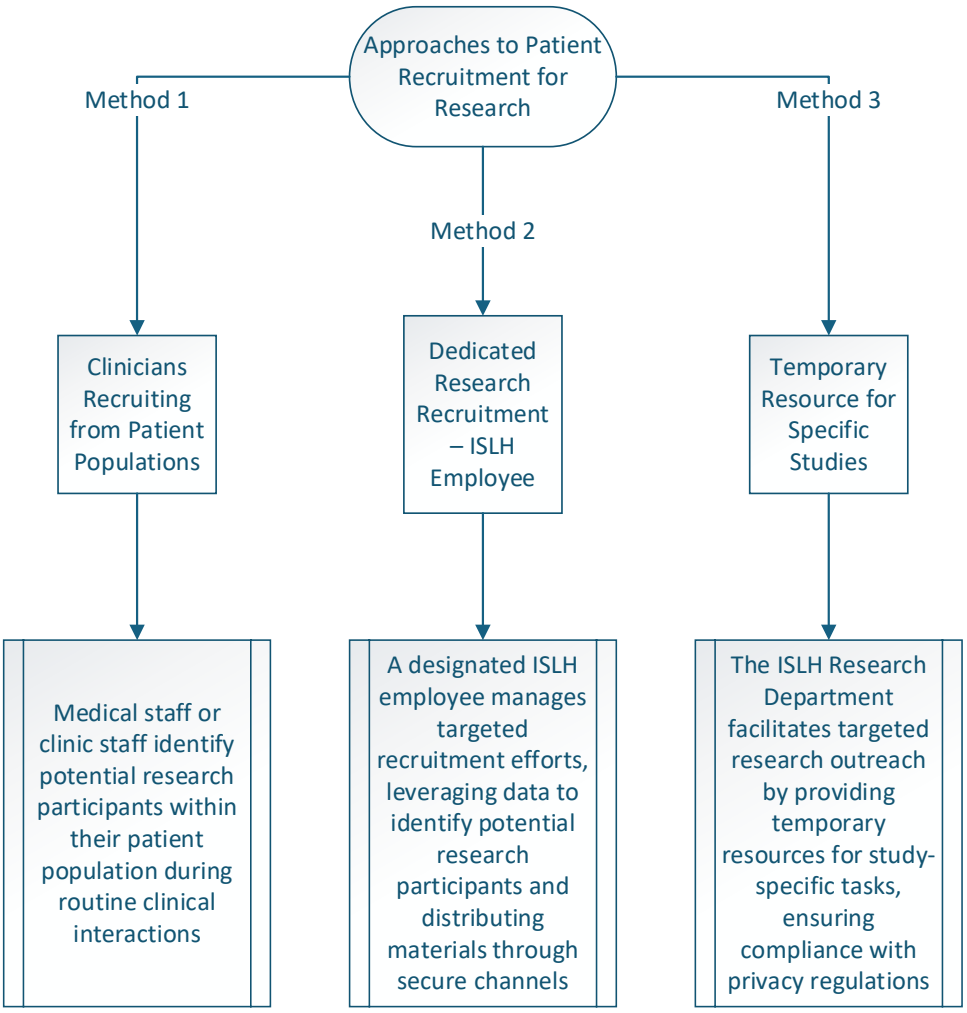

Figure 1 Approaches to patient recruitment for research at Island Health

2.1 Method 1: Clinicians Recruiting from Patient Populations

- **Approach:** Medical Staff (physicians, nurses etc.) will engage directly with patients in clinical settings and/or will send via mail, or email, recruitment material to patients who have received care associated directly with their services area within the last twelve (12) months. Clinical staff (administrative etc.) may, using approved communication mechanisms, send recruitment information to patients regarding relevant research who have received care associated directly with their service area within the last twelve (12) months. This process prioritizes patient autonomy and decision-making regarding research participation. Patients may respond to the clinic, and/or healthcare provider to opt out of future research communications if they do not want to participate.
- **Implementation Steps:**
  - Medical or Clinic Staff Engagement:
    - Using specific criteria based on research project needs (i.e., medical history, age, condition), medical staff or clinic staff identify potential research participants within their patient population during routine clinical interactions.
    - They approach eligible patients with information about specific research projects that align with the patient's medical history or condition.
    - Medical staff may, using approved communication mechanisms communicate with potential participants who access their clinics or services if a research study aligns with the patient's health issue.
  - Distribution of Recruitment Material:
    - Medical staff or clinic staff distribute approved recruitment materials i.e.., pamphlets, brochures) to interested patients.
    - Materials outline research details, potential benefits, privacy protections and inform patients that participating in research will in no way impact clinical care.
    - Medical staff may contact potential participants using a Letter of Initial Contact (Appendix A: Letter of Initial Contact Template) who access their clinics or services if a research study aligns with the patient's health issue.
  - Patient Decision-Making:
    - Patients independently decide whether to reach out to designated research staff for further information.
    - Patient privacy and confidentiality obligations are strictly upheld throughout this process.

2.2 Method 2: Dedicated Research Recruitment - Island Health (ISLH) Employee

- **Approach:** A designated ISLH employee manages targeted recruitment efforts, leveraging data to identify potential research participants and distributing materials through secure channels. This process adheres to strict privacy guidelines to protect patient information.
- **Implementation Steps:**
  - Data Compilation and Analysis:
    - The ISLH employee compiles relevant patient data to identify suitable research cohorts via research requests.

- After completion of a research privacy review, the ISLH employee collects relevant data from the Electronic Health Record (EHR) while maintaining compliance with FIPPA.

- Recruitment Material Delivery:
  - Recruitment materials (i.e., letters, emails) are personalized and sent securely via approved communication mechanisms to eligible participants Using the Letter of Initial Contact.
  - The delivery method respects patient preferences and privacy obligations.
- Follow-Up and Response Management:
  - The ISLH employee coordinates follow-up communications with interested individuals if they are unable to connect with research staff. Privacy related questions/concerns are referred to the ISLH assigned Research Privacy Specialist. Oral Contact Sample Script (Appendix B: Oral Contract Sample Script) is used.
  - The ISLH employee facilitates initial contact between potential participants and research teams while safeguarding patient privacy.

2.3 Method 3: Temporary Resource for Specific Studies

- **Approach:** ISLH Research Department facilitates targeted research outreach by providing temporary resources for study-specific tasks, while the assigned Research Privacy Specialist monitors compliance with FIPPA and its regulations.
- **Implementation Steps:**

1. Resource Allocation:
   - Island Health departments identify research initiatives lacking dedicated recruitment resources.
   - Non Island Health employed research assistants or coordinators are employed by contract to manage specific study outreach.
2. Contact Agreement:
   - Island Health Research Department standardized contact agreement for research team members involved in patient outreach is used (Appendix C: Client Contact Agreement) with accompanying Professional Services Resource Short Form contract.
3. Oversight and Compliance:
   - Research team members adhere to established privacy protocols while engaging with patients.

3.0 Complaints and Concerns

3.1 Concerns about use or disclosure of patient personal information should be directed to the Island Health Information, Stewardship, Access, and Privacy (ISAP) office at privacy@islandhealth.ca or by phone to 250-519-1870 or toll free at 1-877-748-2290.

3.2 Clinicians may also ask the patient if they would like the Island Health ISAP office to contact them about their information-related concern.

3.3 Concerns related to participating in research should be directed to the Research Ethics & Compliance office at researchethics@islandhealth.ca.

4.0 Letter of Initial Contact Process

4.1 Copy and paste the Letter of Initial Contact (Appendix A: Letter of Initial Contact Template) into an Island Health letterhead only (do not include other logos).

4.2 Update the Letter of Initial Contact to reflect your study. Describe your research study in a general fashion without including references to patients' medical history.

4.3 Determine if a Client Contact Agreement is needed. If so, use Appendix C: Client Contact Agreement and work with Research Services at researchandsupportservices@islandhealth.ca to implement a Professional Services Resource Short Form ("PRO") agreement.

4.4 Submit your Letter of Initial Contact and any patient contact scripts (Appendix B: Oral Contract Sample Script) with your REB Approval Application.

4.5 Collect a signature for your Letter of Initial Contact from the Manager, Island Health Patient Services, Program Manager or designated department staff responsible for the patient population of interest. The principal investigator (PI) does not sign the letter.

4.6 Submit the signed Letter of Initial Contact and the signed Client Contact Agreement (if applicable) with your Island Health Application for Operational Review.

4.7 Connect with Decision Support or the relevant clinic or program area to support you in identifying contact information for your cohort.

4.8 Distribution once full Institutional Approval is in place:

4.8.1 Send the Letter of Initial Contact to patients, using approved communication mechanisms.

4.8.2 Email to be sent by Manager, Island Health Patient Services, Program Manager or designated departmental level staff with an Island Health email address.

4.9 Follow up with patients by phone to confirm interest in the study, to provide more information about the study and to make an appointment to review and sign the study's consent form.

4.10 Document all contact made and responses from patients.

5.0 Training

- Review SOP 127 Patient Recruitment for Research and be familiar with related Island Health Standards and References.

6.0 Compliance Monitoring

- The Island Health Manager, Research Ethics & Compliance or their delegate is responsible for ongoing monitoring of Island Health operations to verify compliance with SOP 543 Quality Assurance Auditing.
- The Island Health Manager, Research Ethics & Compliance or their delegate is responsible for communicating any changes to SOP 543 Quality Assurance Auditing to all relevant personnel.
- Deviations from SOP 543 Quality Assurance Auditing will be addressed through corrective and preventative action implementation.

7.0 Definitions

- **Research** - Any disciplined inquiry or systematic investigation intended to extend knowledge or to establish facts or principles that is conducted by Island Health employees, contractors or privileged healthcare practitioner acting in their Island Health capacity. This includes the use of Island Health services articulated in agreements. At Island Health, knowledge translation (evidence to practice) activities are also supported by the Research Department.

8.0 References

- Vancouver Coastal Health Research Institute. (2023). *Vancouver Coastal Health Letter of Initial Contact and Client Contact Agreement [Guidance Document]*. https://www.vchri.ca/sites/default/files/letter-of-initial-contact-guidance-document.docx.Resources
- Freedom of Information and Protection of Privacy Act, R.S.B.C c.165 (1996). https://www.bclaws.gov.bc.ca/civix/document/id/complete/statreg/96165_00

9.0 Summary of Changes

Version	Effective Date	Change Description
1.0	2025-JUN-16	New procedure

Appendix A: Letter of Initial Contact Template

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***USE Island Health LOGO ONLY.** Do not include UBC or any other health authority logos, even for harmonized studies

Dear [insert patient name]

Re: Research Study: [insert title of the study]

You are receiving this letter because you received care, treatment or services at a Vancouver Island Health Authority (Island Health) facility or site. Island Health collects, uses and shares your information in accordance with *British Columbia's Freedom of Information and Protection of Privacy Act*. Alerting patients of research studies taking place at Island Health facilities is directly connected to providing quality care and is aligned with our vision of "A robust, self-sustaining health research community on Vancouver Island, playing an essential role in the delivery of health services, and improving health status and health care for the population we serve".

We are writing to advise you of a study that may be of interest to you, involving [insert a high-level description of what the study involves].

The Principal Investigator of the research study, Dr. [insert the name of the PI] is [insert a description of the PI's position and affiliation with Island Health] (i.e. is a full time ___ physician working within Island Health in the ___ clinic and ___ ward at XXX Hospital).

OR

Dr. [PI's name] is an affiliated investigator and researcher at the [Insert University information].

The research team is trying to determine [insert a brief description in lay terms of the purpose of the study and/or the patient cohort requirements].

For more information about the study or to arrange for your participation, contact Dr. [insert the name of the PI] or the study coordinator [insert the name of the study coordinator] at [insert e-mail and/or telephone number]. Alternatively, you may visit the study website at [insert study URL, if applicable].

Participation in the study is **voluntary**. If you choose not to participate, your care will not be affected in any way.

A study personnel may contact you regarding your interest in this study in the next ___weeks. **If you do not want any further contact by Island Health** regarding this study, please contact [insert e-mail and/or telephone number].

Efforts have been made to ensure this notification does not reach the families of patients who have passed away. If a grieving family member receives this letter, please accept our heartfelt condolences and our sincere apology.

Sincerely,

Manager, Island Health Patient Services, Program Manager, Data Steward, or designated department staff (not Department Head) responsible for the patient area from which the patients were seen.

PI to co-sign if also treating clinician with clinical relationship with the patient.

Appendix B: Oral Contact Sample Script

Introduction

Hello, is this (participants name)? OR Hello, may I please speak to (participant's name)?

Scenario 1: Following up on Letter of Initial Contact if patient is not home

Message response for answering machine

My name is (insert first and last name). I am working with Vancouver Island Health Authority and I am calling to follow up on a letter we sent you regarding a research study. I will call back in the next few days. If you do not wish to be contacted again, please call me directly at [insert contact info for PI or contact].

- Do not mention the clinic or study you represent.
- All patient contact, including messages left on answering machines, should be documented by the research team.
- For certain studies, it may not be appropriate to leave a message in a shared or family mailbox.

Scenario 2: Following up on Letter of Initial Contact and patient is home

My name is (insert name). I am working with Vancouver Island Health Authority's _____ (clinic, unit, site, program where contact information was received). I am following up on a letter sent to you by (name of the Data Steward who signed the Letter of Initial Contact) regarding the (study name).

Do you recall receiving the letter regarding this study?
(If not, exploration as to why not – is the letter still in transit? Was the individual inadvertently missed from the mail out?)

Is this a good time to talk?

(Explain study)

Are you interested in learning more about this study?

Patient says yes to learning more or participating

Can I book an appointment now to review the consent form?

Do you have any further questions that I could answer at this time?

If you change your mind or have any questions about this study, please do not hesitate to contact me. Again, my name is (insert name), the study is_____. My phone number is _____.
Thank you for your time.

Note: Client's response must be documented.

Patient says no to participate

If you change your mind or have any questions about this study, please do not hesitate to contact me. Again, my name is (insert name). My phone number is (provide phone number).

Thank you for your time.

Note: Client's response must be documented.

Scenario 3: Patient is deceased

If you receive a telephone call or are told at any time during a call that the patient you are contacting has passed away, the appropriate language is:

Please accept Island Health's heartfelt condolences and sincere apology. I will ensure this information is updated in our records. If you should have any questions after this call, my name is ____ and my phone number is _____.

Note: Please connect with registration at the ward/clinic where the patient information was received to confirm information about the deceased person is updated in Island Health's records.

Scenario 4: Patient relays that they do not wish to be contacted by Island Health to participate in anything or seems upset by the contact

- Concerns about use or disclosure of patient personal information should be directed to the Island Health ISAP office at privacy@islandhealth.ca or by phone to 250-519-1870 or toll free at 1-877-748-2290.
- Concerns related to participating in research should be directed to the Research Ethics & Compliance office at researchethics@islandhealth.ca.

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Appendix C: Client Contact Agreement

The template to be used is the Island Health **Professional Resource Based Short form template agreement. Ensure the current version is obtained from Contracts, Policy and Standards for each use.**

Client Contact Agreement ("Agreement") For Access and Use of Patient Information to Contact Potential Research Study Participants

STUDY DETAILS:

Principal Investigator: _____

Research Assistant: _____

Research Ethics Board Number: _____

Title of the Research Study (the "Study"), including which patient contact information is required (the "Information"):

_____

WHEREAS:

A. The Principal Investigator would like to contact certain patients as described above in order to enroll participants for the Study;
B. The *Freedom of Information and Protection of Privacy Act* ("FIPPA") prohibits *disclosure* of personal information for research purposes subject to exceptions noted in Section 33(3)(h)(ii)(A)(B);
C. Vancouver Island Health Authority ("Island Health") wishes to facilitate medical research and to connect researchers with study participants as authorized by FIPPA (the "Purpose");
D. Having an individual who is identified in the Study's Research Ethics Board Application, such as a Research Assistant ("Research Administrative Assistant"), contacting potential study participants on behalf of Island Health allows Island Health to inform patients about the Study without disclosing personal information to the Principal Investigator;
E. Island Health agrees to oversee and direct the contacting of potential study participants for the Purpose; and
F. The Research Assistant, when carrying out the Purpose, will be acting as a representative of Island Health and will be working under the direction of Island Health regarding authorized access to and use of the Information for the Purpose.

In consideration of the above, the Principal Investigator and the Research Assistant acknowledge and agree to the following conditions of their access to and use of the Information for the Purpose:

1. A Professional Services Resource Short Form ("PRO"/current template as located in the Island Health contract management resource centre) will be implemented to contract the Research Assistant for purpose of enrolling participants for the Study.

2. For the purpose of contacting potential study participants, the Research Assistant will, at all relevant times, be considered a representative of Island Health.
3. The Research Assistant will perform the Purpose as directed by Island Health.
4. The Research Assistant will only use the Information for the Purpose, and will not use the Information for any other purpose or link the Information with any other information in the possession of the Research Assistant except as authorized by Island Health in writing and in accordance with FIPPA.
5. The Research Assistant understands that the Information is confidential and may not be disclosed to anyone in any manner, including to the Principal Investigator or to other members of the research team working on the Study except as authorized by Island Health in writing and in accordance with FIPPA.
6. The Research Assistant will use reasonable measures to secure the Information and protect it against accidental or unauthorized use or disclosure.
7. The Research Assistant will immediately report to Island Health any loss or potential or actual unauthorized disclosure of Information.
8. The Research Assistant will only retain Information about patients who have consented to participate in the Study per current regulatory guidelines and will destroy all remaining Information, whether in paper or electronic form, immediately upon the completion of the Purpose or otherwise within twenty-four (24) hours of a request from Island Health, and
9. The Research Assistant and the Principal Investigator acknowledge that failure to comply with this Agreement may lead to the revocation of Island Health information access privileges for the Research Assistant and for the Principal Investigator.

If you agree to the above terms and conditions, please indicate so by signing below:

_____	_____
Signature of Principal Investigator	Signature of Research Assistant
_____	_____
Name (Printed)	Name (Printed)
_____	_____
Date	Date

When complete include as an attachment to the Research Operational Approval Application
For privacy questions, contact 250-519-1870 or toll free at 1.877.748.2290 or email privacy@islandhealth.ca