

## Guidance – VCH’s Letter of Initial Contact and Client Contact Agreement

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**Please note:** VCH’s Letter of Initial Contact is just one tool to support recruitment. This process may not be appropriate for all studies, particularly those *studies that do not have an obvious connection to the care that patient has received at VCH or those studies seeking large or historical cohorts.*

## Background

Best Practice for recruiting patients from data received indirectly (i.e. from a private physician or a public body), is to use a Letter of Initial Contact. As outlined in the UBC Clinical Research Ethics Board Guidance Notes, contact should be made by someone who that individual would expect to have relevant information about them (See sections Articles 11.1-11.5).

The Health Authorities and private physicians have ethical and legal obligations to maintain the confidentiality of their patients and must get permission from their patients to release their patient's contact information to third-party researchers. As outlined in Section 35 (1) (a.1) of of British Columbia's *Freedom of Information and Protection of Privacy Act* (FIPPA) public bodies, such as VCH, are prohibited to disclose Personal Information for the purposes of contacting patients to participate in research, unless the individual the information is about has either provided consent to be contacted for this purpose or the BC Privacy Commissioner approves the recruitment strategy. A similar restriction is part BC's privacy law for non-government organizations, including businesses and private physicians offices (see section 21(1)(b) of the *Personal Information Protection Act* (PIPA)).

However, at the Health Authorities, where research is integrated with care, this restriction can create a real burden in terms of process, both for hospital staff, clinicians, researchers and patients.

## Purpose of Guidance:

Vancouver Coastal Health (VCH) developed the Letter of Initial Contact Process for two purposes:

- a) to support researchers recruiting patients for Research Ethics Board (REB) and Vancouver Coastal Health Research Institute (VCHRI) approved studies, where other options for recruitment may be impractical or unreasonable;
- b) To connect patients with research studies that may be of interest to them.

VCH is authorized under FIPPA to contact our patients for purposes consistent with the purpose for which we collected their information. VCH strongly believes that alerting our patients of research studies taking place at VCH facilities that may be of interest to our patient's care is directly connected to providing care.

VCH requires the *Letter of Initial Contact* to come from the VCH Department that is responsible for that patient information. This means that VCH's Letter of Initial Contact must be signed by

the **relevant VCH Department Head** as opposed to the Principal Investigator. In cases where the Department Head is the Principal Investigator or a Co-Investigator, another authorized Operational Lead in the department (usually a Director or Manager) may sign the letter.

VCH departments may not have the resources to actually manage a mail-out or contact our patients about all of the important research initiatives that might be of interest to them. VCH's Legal and Information Privacy Office has developed a process where a member of the research team (usually a research assistant or research coordinator) can sign and comply with an agreement with VCH (the Client Contact Agreement) to manage the mail out and follow up contact on VCH's behalf.

## Process Considerations

One thing to consider before utilizing the Letter of Initial Contact process is whether VCH's records can provide accurate patient contact information.

VCH's patient contact information can only be considered accurate if the patient has recently validated this information in our hospitals or clinics. While patients are asked to validate their contact information at each visit, information takes time to be updated across clinics and systems. For this reason, the Letter of Initial Contact process may not be appropriate for large cohorts, cohorts spanning health regions or organizations, or historic cohorts made up of patients who have not received recent services or care from VCH.

## Alternate Methods for Recruitment

### Recruiting on site on a hospital ward or clinic

VCH recognizes that pre-screening prior to approaching patients about a study helps to reduce the burden on patients. Researchers who have REB and VCH Operational Approval may pre-screen patients to support research recruitment on VCH wards/clinics.

However, external researchers *should not* pre-screen patients and then **directly approach** those patients on a unit floor/clinic to recruit them into the study.

A process at each unit/clinic should be put in place where eligible patients who have been pre-screened are then referred by the care provider/appropriate operational staff member to the research team. The purpose of this is to avoid having the patient approached by someone who they would not *expect* to have information about them.

Where this process has been undertaken, researchers will only approach patients where there has been both a confirmation of basic eligibility and interest in the study on behalf of the patient.

## Ministry of Health (MOH) Patient Recruitment Process

The MOH, in coordination with the BC Office of the Information Privacy Commissioner (OIPC) have developed a process to obtain OIPC approval for studies seeking to recruit participants using MOH data sets and tools including Vital Statistics, the Discharge Abstract Database and MSP data. This process is recommended for large or historical cohorts and those cohorts that span health regions. Visit: <http://www2.gov.bc.ca/gov/content/health/conducting-health-research-evaluation/data-access-health-data-central/academic-researchers/requests-to-contact-bc-residents>

## REACH Platform (formally the The BC Health Research Connection Project)

VCH is leading the REACH Platform Project, formally known as the *BC Health Research Connection Project*, which will create a provincial platform to improve how British Columbians find and connect to health researchers and research opportunities. One component of the platform is to create a provincial research registry in which patients and members of the public can sign up to receive notifications of research opportunities based on their interests and eligibility. For more information, see <http://bcsupportunit.ca/healthresearchconnection/>.

This project will pilot in the spring of 2019. If your clinic is interested in becoming a pilot site for the BC Health Research Connection Project, connect with [Amanda.Chisholm@vch.ca](mailto:Amanda.Chisholm@vch.ca).

## Recruiting from Other Health Authorities

- **Island Health**

Vancouver Island Health Authority (VIHA) maintains a platform to enhance research participant recruitment. To request more information about this platform, contact, Rebecca Barnes, Research Engagement and Outreach Project Manager  
Email: [Rebecca.Barnes@viha.ca](mailto:Rebecca.Barnes@viha.ca); Phone: 250-519-7700 x 12718.  
See: <https://www.viha.ca/rnd/conduct/enrollment.html>.

- **Fraser Health**

Fraser Health Authority requests permission to contact for research purposes at the point of registration at their main registration sites at Jim Pattison Outpatient Care and Surgical Centre, Peace Arch Hospital, Royal Columbian Hospital and Surrey Memorial Hospital Rehabilitation Clinics. Approved Fraser Health Researchers may request a report on all patients who have provided permission to be contacted for research purposes. For more information, visit: <http://www.fraserhealth.ca/health-professionals/research-and-evaluation/how-we-can-help/consent-to-contact/>

## References

### UBC CREB Guidance on Recruiting Patients:

Articles 11.1-11.5 under the UBC CREB's Guidance notes for more information:

<https://ethics.research.ubc.ca/ore/ubc-clinical-research-ethics-general-guidance-notes>

## Appendix A – Letter of Initial Contact Process flow

1. **Download** the *Letter of Initial Contact* from the VCHRI website.  
[https://www.vchri.ca/sites/default/files/template\\_letter\\_of\\_initial\\_contact\\_vcha\\_-\\_final\\_aug\\_02\\_2015\\_0.doc](https://www.vchri.ca/sites/default/files/template_letter_of_initial_contact_vcha_-_final_aug_02_2015_0.doc)
2. **Update** the *Letter of Initial Contact* to reflect your study. Use VCH letterhead or include the VCH logo.
3. **Request** a *Client Contact Agreement* from the VCH Privacy Office ([privacy@vch.ca](mailto:privacy@vch.ca)).
4. **Submit** your letter and any patient contact scripts with your *REB Approval Application*.
5. **Collect** a signature for your *Letter of Initial Contact* from the VCH Department Head responsible for the patient population of interest. The Principle Investigator *does not sign* the letter.
6. **Submit** the signed *Letter of Initial Contact* and the signed *Client Contact Agreement* with your *VCHRI Application for Operational Approval*.  
  
**Connect** with Decision Support or the relevant clinic or program area to support you in identifying contact information for your cohort.
7. **Mail** the *Letter of Initial Contact* to patients.
8. **Follow up** with patients by phone to confirm interest in the study, to provide more information about the study, and/or to make an appointment to review and sign the study's consent form.
9. **Document** all contact with patients.

## Appendix B – Template – Letter of Initial Contact

*Please use VCH logos*

Dear Patient,

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

We are writing to inform you of a study involving *[insert a brief 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 the research institutions]* (e.g. is a full time \_\_\_\_\_ physician working within Vancouver Coastal Health (VCH) in the \_\_\_\_\_ clinic and \_\_\_\_\_ ward at UBC Hospital).

The research team is trying to determine *[insert a brief description in lay terms of what the study is trying to find achieve i.e. what is the purpose of the study]*.

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 Vancouver Coastal Health representative may contact you regarding your interest in this study in the next \_\_\_ weeks. If you do not want **any further contact by VCH** 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,

Program Manager or Appropriately Designated Departmental Level staff  
*[insert name of Department(s)]*  
*[insert name of Institution that has the patients' personally identifiable information]*

Appendix C - Client Contact Agreement



**Client Contact Agreement**  
For Access and Use of Patient Information to  
Contact Potential Research Study Participants

**STUDY DETAILS:**

Study ID#: \_\_\_\_\_

Principal Investigator: \_\_\_\_\_

Research Assistant: \_\_\_\_\_

Research Ethics Board Number: \_\_\_\_\_

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

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**WHEREAS:**

- A. The Principal Investigator would like to contact certain patients as described above in order to enroll participants for the Study;
- B. Section 35 of the *Freedom of Information and Protection of Privacy Act* ("FIPPA") prohibits disclosure of personal information for the purpose of contacting a person to participate in the research;
- C. Vancouver Coastal Health Authority ("VCH") 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"), contact potential study participants on behalf of VCH allows VCH to inform patients about the Study without disclosing personal information to the Principal Investigator;
- E. VCH agrees to oversee and direct the contacting of potential study participants for the Purpose; and
- F. The Research Administrative Assistant, when carrying out the Purpose, will be acting as a representative of VCH and will be working under the direction of VCH regarding access to and use of the Information.

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

- 1. For the purpose of contacting potential study participants, the Research Administrative Assistant will at all relevant times be considered a representative of VCH;
- 2. The Research Administrative Assistant will perform the Purpose as directed by VCH;



3. The Research Administrative 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 Administrative Assistant except as authorized by VCH in writing;
4. The Research Administrative 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 VCH in writing;
5. The Research Administrative Assistant will use reasonable measures to secure the Information and protect it against accidental or unauthorized use or disclosure;
6. The Research Administrative Assistant will immediately report to VCH any loss or potential or actual unauthorized disclosure of Information;
7. The Research Administrative Assistant will only retain Information about patients who have consented to participate in the Study 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 VCH; and
8. The Research Administrative Assistant and the Principal Investigator acknowledge that failure to comply with this Agreement may lead to the revocation of VCH 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  
Assistant

\_\_\_\_\_  
Signature of Research Administrative

\_\_\_\_\_  
Name (Printed)

\_\_\_\_\_  
Name (Printed)

\_\_\_\_\_  
Date

\_\_\_\_\_  
Date

**When complete email to:** [wylo.kayle@vch.ca](mailto:wylo.kayle@vch.ca) and [privacy@vch.ca](mailto:privacy@vch.ca)

For privacy questions, contact the VCH Information Privacy Office at 604-875-5568 or [privacy@vch.ca](mailto:privacy@vch.ca).



## Appendix D - VCH Oral Contact Sample Script

### Introduction:

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

### Scenario 1: Following up on Letter of Initial Contact and Patient is not Home

Message response for **answering machine**.

- Do not mention the clinic or study you represent.

*My name is (insert first and last name). I am working with Vancouver Coastal Health 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 \_\_\_\_\_.*

**Note:** All patient contact, including messages left on answering machines, should be documented by the research team.

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

*My name is (insert name). I am working with Vancouver Coastal Health'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).*

*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 deceased, the appropriate language is:

*Please accept VCH'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 \_\_\_\_.*

\*Please connect with registration at the Clinic/Site where received the patient information to confirm this information about the deceased person is updated in VCH's records.

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

Patients may be directed to the VCH Privacy Office (604) 875-5568 if they wish not to be contacted again in the future for any purpose or seem upset by the contact. You may also ask the Patient if they would like the VCH Privacy Office to contact them about their concern.

Please alert the VCH Privacy Office of these scenarios.

## Letter of Initial Contact Checklist

- Ensure your Letter of Initial Contact and all scripts are approved by the REB and VCHRI.
- Ensure your Letter of Initial Contact is signed by the VCH Department Head who is responsible for the patient data required to identify your cohort and enable recruitment.
- Utilize VCH's Oral Contact Sample Script (Appendix E) for guidance on responding to scenarios for when the patient is not home, or the patient is deceased.
- Track all contact with patients to ensure you are managing patient's wishes appropriately.
- Alert the VCH Privacy Office if any patients have indicated concerns with your contact.
- Ensure you are aware that Health Authorities and some BC Health Agencies have different processes and requirements for recruitment. The Letter of Initial Process at VCH will not necessarily be appropriate in other regions or for cohorts that span organizations.