

Guidance – Vancouver Coastal Health’s Letter of Initial Contact and Client Contact Agreement

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Please note: Vancouver Coastal Health’s (VCH) 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.

Executive Summary

Where a research project seeks to reach out to potential participants, a Letter of Initial Contact is mandatory to ensure alignment with requirements under BC's *Freedom of Information and Protection of Privacy Act* (FIPPA).

The Letter of Initial Contact must come from the health authority, on VCH letterhead. It is an additional step that must occur prior to the researchers contacting patients.

Background

The 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](#)).

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 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 health authorities where research is integrated with care, this restriction can create a burden in terms of process, for hospital staff, clinicians, researchers and patients.

Please direct any questions regarding this guidance document to DRMO@vch.ca.

Purpose of Guidance

VCH developed the Letter of Initial Contact process for two purposes:

- 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; and
- To connect patients with research studies that may be of interest to them.

VCH is authorized under FIPPA to contact patients for purposes consistent with the purpose for which we collected their information. VCH strongly believes that alerting patients of research

studies taking place at VCH facilities that may be of interest to patients 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 manage a mail-out or contact 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 multiple health regions or organizations, or historic cohorts made up of patients who have not received recent services or care from VCH.

Once the Letter of Initial Contact has been issued to potential participants, the researchers may follow up with participants (excluding those who have indicated to VCH that they do not wish to be contacted) using their REB-approved method of contact with details around their specific project.

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 VCH ward/clinic to recruit them into a study.

A process at each ward/clinic should be put in place where eligible patients who have been pre-screened are then referred by the care provider or an 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 Patient Recruitment Process

The Ministry of Health (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 Medical Services Plan (MSP) data. This process, called the [Request to Contact BC Residents](#), is recommended for large or historical cohorts and those cohorts that span health regions.

REACH BC Platform

REACH BC is an online platform that connects health researchers to volunteers who are interested in participating in research. Researchers can post opportunities on REACH BC and find study participants, as well as patient partners.

To recruit COVID-19 patients, REACH BC has established a provincial process to coordinate the communication of health research projects to COVID patients. This process has been approved by Public Health and the BC Centre for Disease Control, and is being coordinated with the provincial COVID-19 Clinical Research Initiative.

Visit [REACH BC](#) for more information or contact Stefanie Cheah, REACH BC Project Manager at stefanie.cheah@vch.ca.

References

UBC CREB Guidance on Recruiting Patients:

See articles 11.1 to 11.5 under the [UBC CREB's Guidance](#) notes for more information.

Appendix A – Letter of Initial Contact Process flow

1. **Copy and paste** the Letter of Initial Contact in [Appendix B](#) into a VCH letterhead.
2. **Update** the Letter of Initial Contact to reflect your study.
3. **Determine if** a Client Contact Agreement is needed. If so, see [Appendix C](#).
4. **Submit** your letter (Appendix B) and any patient contact scripts ([Appendix D](#) Oral sample contact script) 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 principal 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.
7. **Connect** with Decision Support or the relevant clinic or program area to support you in identifying contact information for your cohort.
8. **Mail** the Letter of Initial Contact to patients, following the process agreed upon with the VCH department head.
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.
10. **Document** all contact with patients.

Appendix B –Letter of Initial Contact Template

Please use VCH logos only.

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 (VCH) 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"):

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 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 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 Assistant will at all relevant times be considered a representative of VCH;
2. The Research Assistant will perform the Purpose as directed by VCH;
3. 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 VCH in writing;
4. 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 VCH in writing;
5. The Research Assistant will use reasonable measures to secure the Information and protect it against accidental or unauthorized use or disclosure;
6. The Research Assistant will immediately report to VCH any loss or potential or actual unauthorized disclosure of Information;
7. The Research 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 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

Signature of Research Assistant

Name (Printed)

Name (Printed)

Date

Date

When complete email to: Jad.maanaki@vch.ca
For privacy questions, contact the Data Release Management: DRMO@vch.ca

Appendix D – Vancouver Coastal Health 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 if patient is not home

Message response for answering machine

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. Do not mention the clinic or study your represent.

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 _____.

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 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

If the patient does not wish to be contacted again in the future for any purpose or if the patient seems upset by the contact, patients may be directed to contact the VCH Privacy Office at (604) 875-5568 to discuss their concerns. 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 the Letter of Initial Contact and all scripts are approved by the REB and VCHRI.
- Ensure the 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 for guidance on responding to scenarios for when the patient is not home or if the patient is deceased.
- Track all contact with patients to ensure the patient's wishes are managed 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 Contact Process at VCH will not necessarily be appropriate in other regions or for cohorts that span organizations.