# Guidance Document | Vancouver Coastal Health Letter of Initial Contact and Client Contact Agreement

## 

## Checklist

This checklist includes mandatory requirements for all projects recruiting participants (e.g. patients, staff, etc.) for research or clinical trials at Vancouver Coastal Health (VCH) sites via letter or email. Submit this completed checklist to the Vancouver Coastal Health Research Institute (VCHRI) along with the remainder of your VCHRI [Application for Operational Approval to Conduct a Research Study](https://www.vchri.ca/services/operational-approval).

|  |  |  |
| --- | --- | --- |
| **Initial** | **Mandatory Requirement** | **Reference** |
|  | The Letter of Initial Contact is signed by a VCH Patient Services Manager, Program Manager, Data Steward, or designated department staff (not Department Head) responsible for the patient area from which the patients were seen.  If the Principal Investigator has a clinical relationship with the patient, they may co-sign the letter. | Page 4 |
|  | If the Letter of Initial Contact will be sent from a VCH email address, please include the address: Click or tap here to enter text. | Page 4 |
|  | The Letter of Initial Contact contains only the VCH logo. No other logos should be added, including the UBC logo. | Appendix A  Page 8 |
|  | The Principal Investigator has completed the Client Contact Agreement if contacting patients on VCH’s behalf. | Appendix B  Page 9 |

If you require further guidance or have questions, contact [vchinformationprivacy@vch.ca](mailto:vchinformationprivacy@vch.ca)

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## 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 [Articles 11.1-11.5](https://ethics.research.ubc.ca/ore/ubc-clinical-research-ethics-general-guidance-notes) for more information).

Health authorities have ethical and legal obligations to maintain the confidentiality of their patients and must get permission from their patients to release their contact information to third-party researchers. As outlined in [section 33(3)(h)(ii)](https://www.bclaws.gov.bc.ca/civix/document/id/complete/statreg/96165_03#section33) of the *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 has either provided consent to be contacted for this purpose or the BC’s Information and Privacy Commissioner approves the recruitment strategy.

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. The purpose of this document is to provide clear instructions to researchers and staff on how best to navigate this process.

Please direct any questions regarding this guidance document to [vchinformationprivacy@vch.ca](mailto:vchinformationprivacy@vch.ca).

## Overview of the Process

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 collects information in the course of providing healthcare services.  VCH uses this data to evaluate services and plan for programming, and is authorized under FOIPPA to contact patients to seek feedback or invite them to participate in research studies that may be of interest to them, based on care provided to them at VCH facilities.

VCH requires the [Letter of Initial Contact](#_Appendix_B_–Template_1)(Appendix A) 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 Patient Services Manager, Program Manager or designated department staff (not Department Head) responsible for the patient area from which the patients were seen. If there is a clinical relationship between the patient and the Principal Investigator (PI), the PI may co-sign the letter. If there is a conflict of interest, another authorized operational lead in the department may sign the letter.

In some circumstances (i.e. support from VCH department), it may be appropriate to send the Letter of Initial Contact as an attachment via email. In this case, the email address must always be a VCH email address. It is not permitted to attach the Letter of Initial Contact from a UBC or other health authority email address. Email recruitment will not always be possible or appropriate as many VCH systems do not capture email address and/or the email address of the patient may not recently have been validated, as per [VCH Emailing Policy](http://shop.healthcarebc.ca/PHCVCHPolicies/BD-00-11-40000.pdf).

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. The VCH 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 a Client Contact Agreement with VCH (see [Appendix B](#_Appendix_C_-)) to manage the mail-out and follow up contact on VCH’s behalf.

## Letter of Initial Contact Process Flow

1. **Copy and paste** the Letter of Initial Contact in [Appendix A](#_Appendix_B_–Template_1) into a VCH letterhead only (do not include other logos). See next page for template.
2. **Update** the Letter of Initial Contact to reflect your study. Please describe your research study in a general fashion without including references to patients’ medical history.
3. **Determine if** a Client Contact Agreement is needed. If so, see [Appendix B](#_Appendix_C_-).
4. **Submit** your Letter of Initial Contact and any patient contact scripts ([Appendix C](#_Appendix_D_-) Oral sample contact script) with your REB Approval Application.
5. **Collect** a signature for your Letter of Initial Contact from the VCH Patient Services Manager, Program Manager or designated department staff (not Department Head) responsible for the patient population of interest. The PI does not signthe 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. **Distribute by:**
   1. **Mail** the Letter of Initial Contact to patients, following the process agreed upon with the VCH Patient Services Manager, Program Manager or designated departmental level staff.
   2. **Email** to be sent by VCH Patient Services Manager, Program Manager or designated departmental level staff with a VCH email address.
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 made and responses from patients.

## **Appendix A – Letter of Initial Contact Template**

**\*USE VCH 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 Coastal Health (VCH) facility or site. VCH collects, uses and shares your information in accordance with *British Columbia’s Freedom of Information and Protection of Privacy Act*. VCH strongly believes that alerting patients of research studies taking place at VCH facilities is directly connected to providing quality care.

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 the research institutions] (e.g. is a full time \_\_\_ physician working within VCH in the \_\_\_ clinic and \_\_\_ ward at UBC Hospital).

Dr. [PI’s name] is an affiliated investigator and researcher at the University of British Columbia.

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 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,

VCH Patient Services Manager, 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 – Client Contact Agreement**



**Client Contact 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**:

1. The Principal Investigator would like to contact certain patients as described above in order to enroll participants for the Study;
2. Section 33(3)(h) 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;
3. Vancouver Coastal Health Authority (“VCH”) wishes to facilitate medical research and to connect researchers with study participants as authorized by FIPPA (the “Purpose”);
4. 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 VCH allows VCH to inform patients about the Study without disclosing personal information to the Principal Investigator;
5. VCH agrees to oversee and direct the contacting of potential study participants for the Purpose; and
6. 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: [Coordinator, Research Approvals](https://www.vchri.ca/services/operational-approval)

For privacy questions, contact [vchinformationprivacy@vch.ca](mailto:vchinformationprivacy@vch.ca)

## Appendix C – 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 \_\_\_\_\_\_\_\_\_\_.*

* 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 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).*

*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 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.