

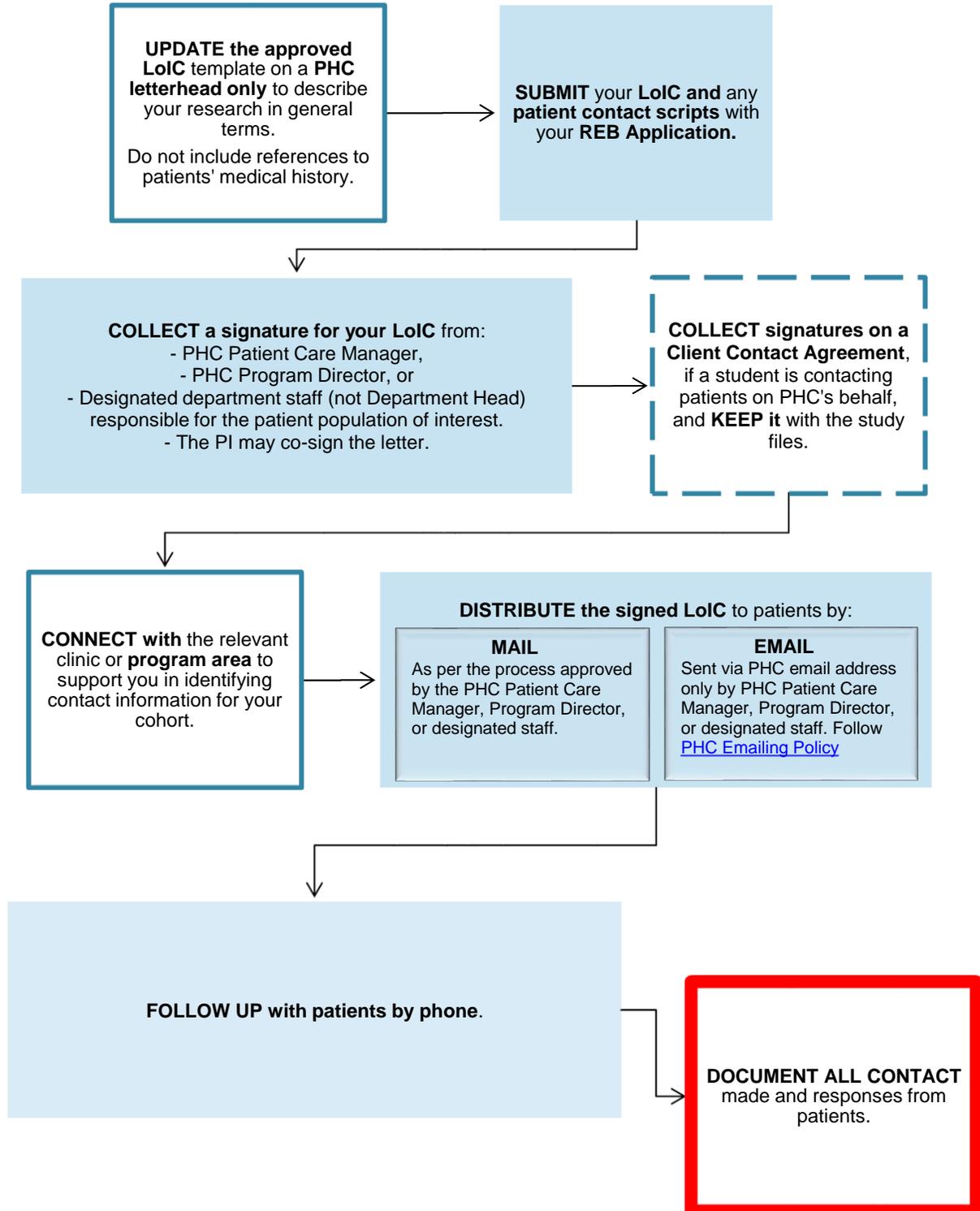


Letter of Initial Contact Process Flow

Providence Health Care (PHC) Information Access and Privacy Office (IAPO) developed the Letter of Initial Contact (LoIC) template and guidance document to support researchers recruiting PHC patients for the Research Ethics Board (REB) and Providence Health Care Research Institute (Providence Research) approved studies, where other options for recruitment may be impractical or unreasonable.

- Please USE PHC LOGO ONLY. Do not include UBC or any other health authority logos, even for harmonized studies.
- Describe study in general terms, do not include references to medical history.
- The LoIC must come from the PHC department that is responsible for that patient information and must be signed by the relevant PHC Patient Care Manager or designated department staff (not the Physician Department Head) responsible for the patient area from which the patients were seen.
 - PI can co-sign if they are also a treating clinician with clinical relationship with the patient.
- Submit LoIC and any patient contact scripts with your REB Application.
- Connect with the relevant clinic or program area to support you in identifying contact information for your cohort.
- PHC departments may not have the resources to manage a mail-out or contact patients. In such cases, a member of the research team (a research assistant or coordinator) can manage the mail-out and follow up contact on PHC's behalf.
 - All team members contacting patients must be listed on REB application, be up-to-date with Privacy Training for VCH & PHC Researchers course on Learning Hub, and signed a Confidentiality Undertaking.
 - Students sending out LoIC or contacting patients on behalf of PHC are required to sign a Client Contact Agreement. Please retain it with the study files.
- In some circumstances it may be appropriate to send the LoIC as an attachment via email, provided that patient's email addresses have been previously authenticated. The sender's email address must always be a PHC email address. [PHC Emailing Policy](#) must be followed.
- 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.
- Document all contact made and responses from patients.

Please direct any questions regarding this guidance document to PHC Information Access and Privacy Office (IAPO) at privacy@providencehealth.bc.ca.



PHC Letter of Initial Contact Template



***USE PHC 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 Providence Health Care (PHC) facility or site.

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 PHC in the ___ clinic.

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 Providence Health Care (PHC) representative may contact you regarding your interest in this study in the next ___ weeks. **If you do not want any further contact by PHC** regarding this study, please contact [insert e-mail and/or telephone number].

[Delete if the Letter is provided in-person] 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,

PHC Patient Care Manager or designated department staff (not the Physician Department Head) responsible for the patient area from which the patients were seen.

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



PHC Follow up on LoIC - Oral Contact Sample Script

ALL PATIENT CONTACT MUST BE DOCUMENTED BY THE RESEARCH TEAM (including voicemails)

PATIENT IS HOME

My name is ____.

*I am working with Providence Health Care (site, source of contact information).
I am following up on a letter sent to you by (name of the PCM who signed the LoIC) regarding the (study name).*

Is this a good time to talk? Are you interested in learning more about this study?

YES
NO
Do not wish to be contacted

CLIENT'S RESPONSE MUST BE DOCUMENTED

Explain the study.

- Do you have any further questions?
- Can I book an appointment now to review the consent form?
- If you change your mind or have any questions, please do not hesitate to contact me. Again, my name is _____, the study is _____. My phone number is _____. Thank you for your time.

Remove from the contact list.

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

Alert the PHC Privacy Office. Remove from the contact list.

- If the patient does not wish to be contacted or if the patient seems upset by the contact, they may be directed to contact the PHC Privacy Office (604-806-8336 or privacy@providencehealth.bc.ca)
- You may also ask the patient if they would like the PHC Privacy Office to contact them about their concern.

PATIENT IS NOT HOME

My name is __. I am working with Providence Health Care 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.
For certain studies, it may not be appropriate to leave a message in a shared or family mailbox.

PATIENT IS DECEASED

Please accept PHC'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 _____.

Connect with registration at the ward/clinic where the patient information was received from, to confirm that the information about the deceased person is updated in PHC's records.



PHC Client Contact Agreement



Client Contact Agreement

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

Principal Investigator [insert PI's name]	Research Team Member (the "Research Assistant") [insert RA's name]	Research Ethics Board (REB) Number [insert REB H number]
Title of the Research Study (the "Study") [insert title of the study]		Patient contact information (the "Information") [list types of contact 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 33(3)(h) of the *BC Freedom of Information and Protection of Privacy Act* ("FIPPA") and section 21(1) of the *BC Personal Information Protection Act* (PIPA) prohibits disclosure of personal information for the purpose of contacting a person to participate in the research;
- C. Providence Health Care ("PHC") wishes to facilitate medical research and to connect researchers with study participants as authorized by FIPPA/PIPA (the "Purpose");
- D. Having an individual who is identified in the Study's REB Application, such as a Research Assistant, contacting potential study participants on behalf of PHC, allows PHC to inform patients about the Study without disclosing personal information to the Principal Investigator;
- E. PHC 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 PHC and will be working under the direction of PHC 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 PHC;
- 2. The Research Assistant will perform the Purpose as directed by PHC;
- 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 PHC in writing;
- 4. The Research Assistant understands that the Information is confidential and may not be disclosed to anyone outside of the research team working on the Study, as approved on the Study's REB Application, and except as authorized by PHC 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 PHC 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 according to the research data retention schedule;
- 8. The Research Assistant will destroy Information about patients who have not consented to participate in the Study immediately upon the completion of the Purpose or otherwise within twenty four (24) hours of a request from PHC; and
- 9. The Research Assistant and the Principal Investigator acknowledge that failure to comply with this Agreement may lead to the revocation of PHC 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

Name (Printed)

Date

Signature of Research Assistant

Name (Printed)

Date