

Guidance: Consent to Access Health Records (Pre-Screening) & Permission to Contact for Research Recruitment



1. Accessing Records to Determine Eligibility (Pre-Screening)

Accessing patient records to determine study eligibility is considered a disclosure of health information under Alberta's Health Information Act (HIA). Therefore, consent is required to access patient records for research purposes (i.e., you cannot just look because you have access as a care provider).

Acceptable Approaches re: consent to determine eligibility:

Real time in clinic visit

If a clinician or health care provider is seeing a patient in real time for a clinical visit, they can review the record for the purpose of determining if the patient may be eligible for the research study.

If the review of records cannot be done in the course of a real time clinical visit the following approaches are acceptable:

Written or electronic consent

Access may be granted when the patient provides written or electronic consent authorizing the use of their health information for eligibility screening. Written consent for screening records to determine eligibility must be study specific. Blanket (clinic wide) consents for the purpose of screening records for eligibility cannot be approved under the HIA, so will not be approved by the REB. (See Appendix A)

Waiver of Consent

Researchers may apply for an REB-approved waiver of consent to access patient records without obtaining individual consent. To be granted, the researcher must justify in the ethics application (Section 4.3) why obtaining consent is unreasonable, impractical, or not feasible. The REB must approve this request.

Verbal consent is not sufficient:

Verbal consent does **not** meet the requirements of the HIA to authorize access to patient records for pre-screening. Researchers must obtain study specific written/electronic consent or an REB-approved waiver.

Who can screen records with a waiver of consent granted by the REB?

Once study specific written/electronic consent is obtained or a waiver of consent is granted by the REB any member of the research team (e.g., PI, Study Coordinator) named in the ARISE application and provisioned access to medical records by the data custodian (e.g., via Connect Care) may perform this screening of patient records to determine eligibility.



2. Permission to Contact Eligible Patients

Once eligibility has been determined, there are a couple of ways that participants may be approached to see if they are interested to hear about a research study.

Acceptable Approaches re: obtaining permission to contact eligible patients:

Clinic/Program Wide Permission to Contact form (See Appendix C)

Researchers may choose to implement a clinic wide (sometimes referred to as “blanket”) Permission to Contact form within the clinic/program in which they work. Permission to Contact informs clinic patients that research is done in the clinic, and seeks their consent to contact them if they may be eligible.

Permission to Contact forms do not give consent to screen records. If you are implementing a clinic wide Permission to Contact process, your REB applications must reflect an approved waiver of consent to screen records in Section 4.3.

With Permission to Contact forms in place, the research team can reach out to eligible patients to see if they want to hear more about the study once eligibility is confirmed.

Research groups may partner with the Alberta health entity department/clinic to store Permission to Contact Lists in Connect Care. See [Research Permission to Contact Lists Quick Start Guide \(sharepoint.com\)](https://sharepoint.com) for additional guidance. This workflow is only available when the health entity manages the PTC list in Connect Care. Additional requirements for the consent form apply.

Someone from the patient’s clinical care team/data custodian approaches patient

- **If you do not have a signed Permission to Contact, only someone in the patient’s clinical care team (the patients clinical care provider or an employee of the data custodian (ie. “AHS intermediary”)) may approach the patient to:**
 - Inform them about the study.
 - Ask if they wish to be contacted by the research team.

If the patient says **YES**:

Acceptable Approaches:

Written consent

- The patient signs a study-specific *permission-to-contact* form (See Appendix B). The form either (a) meets HIA §34 consent-to-disclose requirements *or* (b) lets the patient write a preferred phone number.
- The research team may use the number on the form or, where (a) applies, the number already in Connect Care, because they have written consent. Best practice: AHS intermediary will

document this in the patient chart and/or provide the study specific permission to contact form to the research team.

Verbal consent

- **Outpatient setting:**

The patient provides a preferred phone number. The AHS intermediary records and securely gives it to the research team.

 **Note:** With verbal consent, even with an REB-approved **waiver of consent for screening**, the research team cannot access the patient's contact information in the medical record without the written consent of the patient. Only the number provided verbally by the patient may be used.

- **In-patient setting:**

If the patient agrees to a researcher coming to talk to them while they are in hospital/clinic, the AHS intermediary informs the study team of the room number or patient location.

Documentation of Verbal Consent

The AHS intermediary must document the verbal discussion in the patient's chart. Examples:

- *"Approached the patient to inquire about their interest in participating in a clinical trial. The patient expressed interest and agreed to be contacted by the research team for further information."*
- *"The patient was informed by {clinical staff/bedside RN} about the possibility of participating in a research study. They consented to having the research staff reach out to them for more details."*

For either approach above, when the research coordinator makes contact:

- First, confirm you are speaking with the correct patient who gave permission to be contacted.
- Only after confirming identity may you proceed to mention the study and discuss participation.

APPENDIX A: Study Specific Consent to Access Medical Records for Eligibility Screening

Study Title: [Insert title]

Principal Investigator(s): [Insert names]

Researchers at the University of Alberta are conducting a research study. In order to know if someone qualifies to participate, they have to review certain information in a patient's medical records. This form is for you to provide consent for the research team to access your medical records for the purpose of determining if you meet the basic eligibility criteria for this study.

If you meet the basic eligibility criteria, someone from the study team may contact you to tell you more about the study so that you can decide if you wish to take part.

Providing this consent is completely voluntary. Choosing not to provide it will not affect your care in any way.

By signing this form:

- I confirm that I understand the purpose of this consent is to allow the disclosure of my health information to the research team named above so they can determine if I am eligible for the study described above.
- I understand that I am providing this consent voluntarily, and I may withdraw it at any time by notifying my care provider or the research team.
- I understand that the research team will access only the minimum necessary health information from my medical records to determine my eligibility.
- I understand that if I meet basic eligibility criteria, a member of the study team may contact me to provide more information about the study.
- I authorize the disclosure of the following information: my name, relevant health information from my medical record needed to determine eligibility, and my contact information if I meet the basic eligibility criteria.
- I authorize this information to be disclosed to: [Insert name of research team or institution].
- I authorize this disclosure to occur once and only for the purpose of determining my eligibility for the study and contacting me if I am eligible.

Patient Name (printed): _____

Patient Signature: _____ Date: _____

Person Obtaining Consent:

Name (printed): _____

Signature: _____ Date: _____

Study Specific Permission to Contact

Study Title: [Insert title]

Principal Investigator(s): [Insert names]

This form is for you to provide consent for the study team to contact you to tell you more about a research study and see if you may be interested in taking part.

Providing your contact number or allowing access to your contact information is completely voluntary. You do not have to provide this information, and choosing not to will not affect your care in any way.

This is not a consent to participate in the study itself. You are only agreeing to be contacted to receive more information.

By signing this form:

- I confirm that I understand the purpose of this consent is to allow the disclosure of my name and contact information to the research team named above so that they may contact me about this study.
- I understand that I am providing this consent voluntarily, and I may withdraw it at any time by notifying my care provider or the research team.
- I understand that my contact information will be used only for the purpose of contacting me about this research study.
- I authorize the disclosure of the following information: my name and EITHER:
 - the phone number I have written below, OR
 - the phone number listed in my Connect Care record (if checked)
- I authorize this information to be disclosed to: [Insert name of research team or institution]
- I authorize this disclosure to occur once and only for the purpose of research recruitment for the study described above.

☐ I am providing my preferred phone number below for contact purposes.

Phone Number (preferred contact number): _____

OR

☐ I consent to the research team accessing the phone number in my Connect Care record to contact me.

Patient Name (printed): _____

Patient Signature: _____ Date: _____

Person Obtaining Consent:

Name (printed): _____

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Signature: _____ Date: _____

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Blanket/Clinic Wide Permission to Contact for Research Studies

The area of [NAME SPECIALTY] is continually advancing through research studies that evaluate new treatments and approaches to care. Your specialist may be currently involved in one or more research studies to improve the understanding and treatment of XX CONDITION.

Participation in research is voluntary. Some patients choose to participate because they are interested in contributing to medical knowledge or possibly being able to be part of a study to test new treatments. However, participation in research is not required and choosing not to participate will not affect the care you receive from your healthcare team.

Permission to Contact About Research

If you choose, you may provide permission for research staff to contact you about research studies that may be relevant to your condition, or which you may be eligible to consider participating in.

If you agree to be contacted, research staff may review your medical record, as approved by a Research Ethics Board, to determine whether you may be eligible for a particular study. This review would only occur for studies that have received the necessary ethics and institutional approvals.

Any information accessed during this process will be used only to determine potential eligibility for research studies, and will not be shared outside of the research office.

If you appear to be eligible for a study, a member of the research team may contact you to provide more information. At that time, the study will be explained in detail, including any potential risks and benefits. You will then be able to decide whether or not you wish to participate.

Choosing not to sign this form will not affect your medical care in any way.

ENTER ADDITIONAL DETAILS:

- **Where the list will be kept**
- **The process whereby the patient can contact to unenroll from permission to contact**
- **That the list will not be shared outside of the research group/program/clinic named in this form**

Your Decision

Please indicate your preference below.

☐ Yes, I agree that the research group may contact me about research studies related to my condition.

☐ No, I do not wish to be contacted about research studies.

If you choose to be contacted, please provide your preferred contact information below.

Name: _____

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Phone Number: _____

Signature: _____

Date: _____