

Department of Pediatrics Guidance for Using Department Lists (Permission to Contact) in Connect Care

Within Connect Care, it is possible to set-up department-specific lists of patients/families who have given permission to be contacted (PTC) about research opportunities. This facilitates study recruitment because researchers can directly contact potential study participants who have given PTC. Researchers cannot contact patients/families directly unless they have given PTC.

PTC lists remove barriers to participant recruitment for University-based researchers. However, this functionality also presents a number of concerns if the lists are not managed appropriately. The Department of Pediatrics supports the use of department lists for PTC, provided that users adhere to the guidance from AHS and the Department. No one is required to use this function in Connect Care.

PTC Guidance – setting up a new list or moving an existing list into Connect Care

Step 1: Review the [AHS guidance for Permission to Contact lists](#)

Step 2: When ensuring no previous PTC lists exist for that department/area, please contact the appropriate AHS Clinical Manager as well as the Department of Pediatrics Sr. Research Consultant, Nicole Romanow (ntr.romanow@ucalgary.ca). This is to avoid unnecessary duplication of lists within a single department/area. Some areas may justifiably have more than one PTC list (e.g., condition/disease specific lists). This will be discussed with the researchers, AHS Clinical Manager, and Sr. Consultant.

Step 3: When identifying individuals (2) who will maintain and manage the list, try to include clinical (AHS) and University employees (researchers), to enable cooperation. These individuals will be the primary contacts regarding the list.

Step 4: Set up the new PTC list, or transition existing PTC list into Connect Care.

Step 5: We encourage ACH-based lists to use the [Department of Pediatrics PTC form template](#). If you would like to develop an area-specific form, please discuss this with the AHS Clinical Manager for the area and the Sr. Consultant (see step 2).

PTC Guidance – requesting PTC

Step 1: Review the [AHS guidance for Permission to Contact lists](#)

Step 2: An AHS employee with whom the patient/family interacts during their hospital visit should collect PTC. Ideally, patients/families should be asked about PTC after their visit with the physician to avoid taking up appointment time.

Step 3: The patient and parent/caregiver should be involved in the decision. Similar to the research ethics board (REB) requirement for pediatric assent to participate in research studies, generally, minors under 14 years of age should be asked to provide assent. For patients 14 or older, a decision-making capacity approach should be adopted to determine whether or not the patient has the competency to decide independently. Patients and parents/caregivers may use a single PTC form that uses age-appropriate language and can be completed and signed by all involved in the decision.

Step 4: Answer questions or refer the patient/family to someone who can (e.g., researcher). See the FAQ section at the end of this document. Ensure the patient/family understands the difference between “permission to contact” and “consent to participate in a research study”.

Step 5: Written documentation is required and must be scanned into the patient record. Patients/families should be asked to reaffirm their PTC decision each time they are contacted through the list by a researcher, or at minimum once per year.

PTC Metrics and Evaluation

When a PTC list is established, we encourage the list manager(s) to conduct ongoing monitoring. This is important to evaluate the process, gauge responsiveness, and measure success in enabling participant recruitment. Ideally, the monitoring process should consider three stakeholder groups:

- 1) Patients/Participants
 - a. Overall PTC acceptance (yes/no) rate for each list. Denominator should be number of patients invited to provide PTC.
- 2) Clinicians/Clinic staff
 - a. Staff involved in the PTC process should be invited to provide feedback and suggest improvements to the process. Information on workload/impact on clinical workflows should be noted. The process for collecting this information should be discussed with the AHS Clinical Manager for the area.
- 3) Researchers
 - a. Research utilization of PTC lists should be documented and the following data should be collected:
 - i. Number of studies accessing the list per year
 - ii. Number of investigators accessing the list per year
 - iii. Number of successful enrollments per contact through PTC list

The Department of Pediatrics can support PTC list metrics collection and evaluation. Please discuss this with the Sr. Consultant when setting up a new list.

If you have questions about the use of PTC lists, please reach out.

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Frequency Asked Questions – How to answer patients/family questions

Question: What is PTC?

Recommended response: For patients/families, PTC is a way to let their care team know they are interested in learning about research opportunities in a specific clinical area. For researchers, PTC is an efficient way to pre-screen patients to facilitate their participation in research. It aims to enhance and simplify research recruitment processes.

Question: How does it work?

Recommended response: Patients are asked for their permission to have researchers access their health record to i) determine if they are candidates for a particular research study, and ii) contact them about research study opportunities.

Question: What identifiable data is collected?

Recommended response: The minimal set of data to enable the PTC program to ensure accurate identification of participants. Typically, this will include participant name, their provincial health number, name of treating physician, contact information, and clinical area. If the patient is contacted about a study and provides consent, then the research team may access additional information relevant to the study.

Question: Will I be asked for PTC each time I come to the hospital?

Recommended response: It is possible that patients/families who visit multiple areas of the hospital will be asked more than once if they want to be on the list for each specific department. The hospital has a streamlined process for requesting PTC and keeps track of which clinical areas have lists. This should help ensure patients/families are not asked about the same list more than once, unless it is to confirm they are still willing to be included on the list.

Question: What is the process for opting in/out?

Recommended response: To opt in, the patient/caregiver will be asked to complete a form which will be uploaded to the clinical information system and attached to the patient's medical chart. To opt out, the patient/caregiver can request to be removed from the list by contacting the clinic they initially opted in with.

Question What is the method of contact?

Recommended response: Patients/caregivers can indicate their preferred contact method. The options include phone or email. It may also be possible to arrange to speak with researchers by video call.

Question How many times will I be contacted about research studies?

Recommended response: Patients/families may be contacted multiple times per year, or not at all. It depends on how many studies in the clinical area use the lists to recruit participants.

Question How is this different from consent to a participate in a research study?

Recommended response: Permission to contact is *before* research consent. At this stage, the patient is asked if they are OK to be contacted about studies for which they may be eligible. If a researcher

contacts them, they will be provided with information about the specific study and asked if they want to participate (consent).

Question What is the commitment?

Recommended response: For now, there is no commitment. If they are contacted about participating in a study, the researcher will outline the expectations and commitment for that specific study before asking if they want to give consent to participate.

Question Is my medical team involved in the research?

Recommended response: The medical team may or may not be involved in research studies about which the patient is contacted. The medical team may or may not know you agreed to be contacted about research. The patient is encouraged to discuss their participation in research with their medical team.

Question What types of studies will I be asked about?

Recommended response: Patients may be asked about several different types of research including but not limited to: surveys, interventional studies, clinical trials.

Question What are the consequences of opting in/out?

Recommended response: There is not impact to medical care. If they decide to give permission, they may be contacted about research opportunities. If they do not give permission, they are less likely to get information about research studies.

Question Who do I contact if I have questions about this process?

Recommended response: They can contact the Department of Pediatrics Sr. Research Consultant, Nicole Romanow (ntr.romnow@ucalgary.ca).

Question: Does a patient's PTC decision expire?

Recommended response: The PTC decision is a step that precedes a full and informed research consent process. The PTC decision remains in effect until it is withdrawn. A recommended best practice is to reaffirm the participant's PTC decision each time they are contacted through the list by a researcher, or at minimum once per year. There is a clearly communicated process through which participants may withdraw their PTC at any time.

Question: How are PTC decisions recorded?

Recommended response: Patients' PTC decision status (yes, no, unknown) is recorded along with a limited set of data within the Clinical Information System (Connect Care). This is a secure system where patient health information is stored.

Question: Is a PTC participant's entire chart looked at?

Recommended response: No, just the essential information in order to pre-screen patients for a particular research study (i.e., the specific inclusion/exclusion criteria).

Question: Can PTC participants be pre-screened for any type of research study?

Recommended response: The PTC decision is at the department/clinic level. Patients will be screened for that specific therapeutic area, for multiple different types of research studies.