# C&W In-Person Recruitment Best Practices

This document is a resource guide for research teams at BC Children's Hospital and BC Women's Hospital + Health Centre (C&W) approaching PHSA patients and families in outpatient clinic and in-patient settings for participation in research studies reviewed and approved by the C&W Research Ethics Board (REB).

In addition to obtaining REB approval, teams wishing to approach PHSA patients and families for research participation must obtain institutional approval prior to starting study activity. To obtain institutional approval, research teams must submit a program utilization form(s) to the relevant program area(s) detailing how eligible participants will be approached for research invitation. Program utilization forms can be accessed here.

## Overview

All patient groups at PHSA regardless of their race or ethnic background, their disease type/condition, geographic location, sexual orientation, gender identity, age, beliefs, and abilities etc. have the right to participate in and benefit from scientific advancements (United Nations General Assembly, Universal Declaration of Human Rights, 1948, Article 27).

PHSA conducts and supports world-class research as part of its Mandate in support of advancing life sciences and health system improvement. At BC Children's Hospital and BC Women's Hospital + Health Centre, we recognize that research is an important part of what we do to improve care.

Research requires participation from diverse populations to make research findings generalizable and more applicable to clinical care. According to TCPS-2, no groups should be unfairly excluded from the potential benefit of research participation, and excluding participants for reasons unrelated to the research question is against the principle of justice and compromises the reliability and usefulness of research results (Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans –TCPS2, 2022, Chapter 4).

The C&W Right to Participate In-Person Recruitment Best Practices Document was developed to ensure that all patients are respectfully invited to participate in research opportunities that require their consent and may be of interest to them.

## Who can use this process?

The Right to Participate (RTP) in-person recruitment process can be used by:

- A PHSA Staff or PHSA-Affiliated Associate.
    - A PHSA-Affiliated Associate is defined as "any BC researchers holding membership status with of the five PHSA research entities (BC Cancer, BCMHSUS, BCCHR, BCCDC, WHRI)" (Page 19, PHSA Data Governance Framework).
    - To hold membership status with BCCHR, a member of the research team can register with BCCHR via the onboarding portal here.

    - To learn about WHRI Membership, including how to become a member, please visit our membership page.
- REB & institutionally approved research studies requiring informed consent where the research has direct implications for improving the health of individuals, the health system or services planning.
    - For more information about obtaining Research Ethics Approval see here.
    - For more information about obtaining Institutional Approval see here.

The RTP in-person recruitment process does not apply in the following contexts:

- Studies that seek to contact individuals for early phase I or II interventional clinical trials if it is unlikely to direct care at an existing or planned program. In these instances, it may be more appropriate to rely on other recruitment processes, for example, where invitation may come directly from circle of care clinical staff.
- Contacting patients to inform them about a research study that aims to collect population/epidemiological factors without such information being used to direct, improve or evaluate health outcomes, or a PHSA program or service.
- External users (non-PHSA researchers) requesting access to patient personal or health data. In this instance, access to patient data may only be given with patients' explicit consent or by signing an agreement created by PHSA Legal. Any external users will be referred to PHSA legal and privacy for appropriate approvals.

## Getting Started

Best practices for in-person study recruitment developed by the Right to Participate Initiative are outlined below in both ambulatory clinic and in-patient settings. Firstly, this section highlights some key things research staff should know, particularly those new to working at the C&W site:

### Access to Information Systems

- PHSA Staff or "PHSA-Affiliated Associates" as defined in PHSA Data Governance Framework can access clinic/patient information for the purposes of screening and identifying eligible participants for studies.
- Research team members must be onboarded via PHSA and hold a valid PHSA network ID and account in order to be granted access to PHSA clinical information systems.
    - For more information on requesting access to clinical information systems go here.
- Research team members must be listed in the approved REB application and/or in a list maintained by the research team of all active research team members as per research ethics requirements. Note that access will be granted only after the study has been approved by the REB.
- Access to other information systems, including clinic-specific databases or provider patient lists can be requested as part of the program utilization approval, which is a requirement of each study in order to obtain Institutional approval.
- Access to patient information must be on a need-to-know basis.

### Staff Training

- Prior to starting any study recruitment, research staff must receive adequate training on and support in the recruitment activities and processes that will be utilized in the study. Where

relevant, they should also be provided with a general orientation to the specific unit or program where they will be working.

- Research staff are responsible for requesting further training through their Supervisor, when identified, in order to perform their job functions.
    - Institutional resources are available to support training in specific areas (i.e. informed consent).
        - For a full list of required training and institutionally available training opportunities for clinical research staff working at C&W see here.

      It is recommended that all research staff maintain up-to-date individual training records. A Training Log template can be found here.

## Clinical Program Engagement

- When utilizing the RTP in-person recruitment process, research team members should be familiar with the clinical workflows and procedures in the program or area where these activities will occur.
- As part of the institutional approval process, clinical operations leaders must be engaged to provide orientation and guidance on how best for research team members to approach eligible patients and families for research within the specific context of the clinic/program and/or address any other relevant safety concerns.
- It is also the responsibility of research team members to ensure that clinical teams, including direct-care staff are oriented to all studies occurring in a given clinic/program. Even where direct-care staff are not being asked to support any specific study activities, direct-care staff should at least be provided the opportunity to learn about the purpose of the study as well as any findings, following completion of study activities.
    - New research team members should be introduced to and are encouraged to build relationships with clinical leaders and clinical educators in areas they will be working in. In this way, research team members can work collaboratively with local leaders and educators to disseminate information about ongoing study activities.
        - Contact crsuadmin@bcchr.ca if you are not sure who the nursing educators/leaders are in your unit/area.

## Coordination with Other Research Teams

- Where possible, individual research teams should make an effort to:
    - Coordinate research approaches with other research teams working in the same unit, so as to avoid overwhelming the patient with multiple research teams approaching patients about different research opportunities concurrently.
    - Communicate any identified preferences about research involvement expressed by patients and families to other research teams working in the same area, so that, to the extent possible, these preferences can be respected.

## Research Study Registration on [Participate in Research]

Having a research study posted on the institute websites improves study visibility and allows patients and families to verify if the study(ies) presented to them is/are institute-approved. However, this is not a requirement for in-person recruitment processes.

- BCCHR Research teams wishing to post public information about ongoing studies, may register the study(ies) on the Participate in Research website to ensure that the study(ies) is/are visible to patients and families.
    - All language that is posted publicly on this website, must **FIRST** be approved by the REB. To register your study(ies) on the [Participate in Research] website, please contact BCCHR Research Communications Team at comms@bcchr.ca.

## Permissible Recruitment Best Practices

Recognizing that each clinic and/or inpatient area may have different clinical workflows, research teams must work closely with clinical and operational leaders in their respective area to ensure that RTP recruitment processes can be seamlessly integrated with existing clinical workflows. Where necessary, the processes described below may be amended or adapted slightly to support this positive integration. The final recruitment process must always be reviewed and approved as part of both REB and Institutional approval process (see Appendix A).

Research teams wishing to utilize the RTP processes are recommended to engage with relevant leaders early on to discuss how each study can be effectively operationalized within the clinic, unit, or program. In addition to the description below, a workflow diagram depicting the RTP recruitment processes can be viewed in Appendix B. Research teams may wish to use or adapt this workflow to facilitate discussions with program leadership about these processes and/or to clarify the steps that will be undertaken for a particular study to the REB.

### Ambulatory Setting

With REB and institutional approvals in place, the following in-person recruitment practices are permissible:

- If appropriate, integrate standard research language (Appendix C) into the existing clinic welcome package, or routine clinic appointment reminder to inform clinic patients of the possibility of being approached for research opportunities during their clinic visit.

- Before any specific study invitations are shared with patients, research team members MUST first connect with a member of the care team to confirm participant eligibility, and ensure the appropriateness of the timing of the approach.
    - Where required (as identified through the Program utilization approval), research staff will confirm the potential participant's study eligibility by reviewing eligibility with a care team member to ensure that only patients who met the eligibility criteria are approached and presented with study information.
    - While it may be appropriate in some instances for research team members to review and confirm eligibility via a clinical database, admission log, or the health record, no patient may be approached without the C&W care team responsible for this patient having knowledge that the patient is to be invited into the study.

- Where appropriate, include specific study information (e.g. study poster, study brochure, letter of initial contact) in the specific clinic appointment reminder communication sent out by the

clinic clerk to eligible patients and families in advance of the clinic visit, allowing for additional time for patients and families to consider study participation.
    - All recruitment materials, study invitations, posters, etc. MUST be REB approved prior to being provided to patients and families.
    - See Appendix D for tips and guidelines for creating study posters and brochures.
    - See Appendix E for a letter of initial contact template that can be adapted for use.

- After connecting with a member of the care team to confirm eligibility and timing, research staff may directly approach eligible study participants to explain and introduce studies without the need for circle of care team introduction.
    - Research team members should document all research encounters in a Screening Log (Appendix F) or Research Recruitment Communication Log (Appendix G).

- Where possible, individual research teams should make an effort to coordinate research approaches with other research teams working in the same clinic/area, as described in the "Getting Started" section above.

- External Users (members who are not PHSA staff or PHSA-Affiliated Associates) are not allowed to directly approach patients and are required to be introduced to the potential participant through a member of the care team (and this must be approved by PHSA legal on a case-by - case basis). A member of the care team must request verbal permission from the potential participant prior to the initiation of any discussion regarding the study.

- Patients may be informed that there are many ways to be approached for research including by others external to the existing research team, and that declining this study would not prevent them from being approached again in the future about other potential research opportunities. See RA Decline Script (Appendix H) for guidance on language to inform patients and families.

### In-patient Setting

With REB and institutional approvals in place, the following in-person recruitment practices are permissible:

- If appropriate, integrate standard research language (Appendix C) into the existing welcome package to inform new patients and families that research is ongoing in the program and that they may be invited to participate in research opportunities.

- Before any specific study invitations are shared with patients, research team members MUST first connect with a member of the care team to confirm participant eligibility,
    - While it may be appropriate in some instances for research team members to review and confirm eligibility via a clinical database, admission log, or the health record, no patient may be approached without the C&W program care team responsible for this patient having knowledge that the patient is to be invited into the study.

- Prior to approaching eligible participants, the research staff MUST also connect with a member of the care team BEFORE entering patient rooms to ensure that the timing to approach is appropriate for study introduction.

    - Should the timing be inappropriate such that the patient is preparing and/or recovering from a procedure, and/or recently received upsetting news, and/or has not yet received information relevant to study eligibility (ie. a specific medical diagnosis), research staff should follow the advice of the care team to identify a more respectful time to approach the patient about the research opportunity.

- Research team members should document all research encounters in an Enrollment Log (Appendix I) or Research Recruitment Communication Log (Appendix G).
    - Where possible, individual research teams should make an effort to coordinate research approaches with other research teams working in the same clinic/area, as described above.

- External Users (members who are not PHSA staff or PHSA-Affiliated Associates) are not allowed to directly approach patients and are required to be introduced to the potential participant through a member of the care team (and this must be approved by PHSA legal on a case-by -case basis). A member of the care team must request verbal permission from the potential participant prior to the initiation of any discussion regarding the study.

- Patients may be informed that there are many ways to be approached for research including by others external to the existing research team, and that declining this study would not prevent them from being approached again in the future about other potential research opportunities. See RA Decline Script (Appendix H) for guidance on language to inform patients and families.

## Documentation

Documentation of research recruitment processes, including identifying eligible participants, tracking consent and enrollment, and refusal and attrition of participants is important as it helps to demonstrate data integrity, consistency, accuracy and reproducibility in the research team's processes. It also aligns with principles of responsible conduct of research and ensures compliance with regulatory requirements (Bradford *et al*., 2021; Bargaje C, 2011).

Furthermore, it is imperative that research teams collect and document the names of individuals who do not wish to participate in a study so as to ensure they are not again approached for invitation into the same study.

- The Screening log is intended to document and identify all participants involved in screening (whether included or not) and their recruitment statuses (i.e. not yet approached, approached, consented, excluded, declined…etc.). This log should also include the reasons for screening failures such as study ineligibility, participation declines and any other relevant reasons. An up-to-date screening log serves as an audit-trail of the study recruitment process and an opportunity to ensure representative samples of participants to improve recruitment strategies where necessary.
- The Enrollment log is intended to list all enrolled participants chronologically by the study ID only for each participant. The up-to-date enrollment log serves as a tool to track study participation status (enrollment, study visit timepoints, early withdrawals…etc.) for each participant for study progress report purposes.

- The Research Recruitment Communication Log (Appendix G) is intended to be a shared document used by multiple research teams working in the same area. It includes documenting individuals approached and the narrative outcomes of each encounter, including whether or not an informed consent discussion occurred, and if not, an optimal time to re-approach and/or follow up. Research team members can also document patients who may have an express wish to not be approached about any research opportunities at all, or whether or not having an interpreter present may be important for any follow-up conversations.

## Data Safeguards

As recruitment materials including Research Recruitment Communication Log (Appendix G), Research Screening Log (Appendix F), and Research Enrollment Log (Appendix I) contain identifying patient information such as patient names, contact information, MRN, PHN…etc., all recruitment materials must be stored securely as follows:

- All electronic recruitment materials must be stored in a password-protected document on secured files on the PHSA and/or BCCHR network drives and computers.
- All hard copy recruitment materials containing identifying information and/or BCCHR/PHSA laptop computer must be securely stored in a locked office of the building requiring key card access. Hard copy recruitment materials will be stored in a locked cabinet in the office.

A privacy breach occurs when private or identifiable information has been shared (accidentally or otherwise) in a way that is outside of the REB approved research protocol. Therefore, is it considered a protocol deviation and must be reported to the REB in addition to the local privacy authorities.

In the event of a privacy breach, research teams can:

1) Submit the privacy breach as a "Request for Acknowledgement" to the REB board of record.
2) Report to the PHSA Privacy office by completing the Privacy Breach Reporting Form here and send to privacy@phsa.ca.

For more information on how to deal with a privacy breach, visit Dealing with a Privacy Breach.

## References


1. United Nations General Assembly. (1948). Universal Declaration of Human Rights (Art. 27). Available at the United Nations.
2. Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, TriCouncil Policy Statement: Ethical Conduct for Research Involving Humans, December 2022.
3. Bradford, N., Cashion, C., Condon, P. et al. Recruitment principles and strategies for supportive care research in pediatric oncology. BMC Med Res Methodol 21, 178 (2021). https://doi.org/10.1186/s12874-021-01371-1
4. Bargaje, C. Good documentation practice in clinical research. Perspect Clin Res. 2011 Apr-Jun; 2(2):59-63.

## Version History

| Version | Change Made | Reason for Change | Contributing Authors |
|---|---|---|---|
| April 24, 2025 | New document | New document | Monica Ho<br>Jennifer Claydon<br>Jesse Veenstra |
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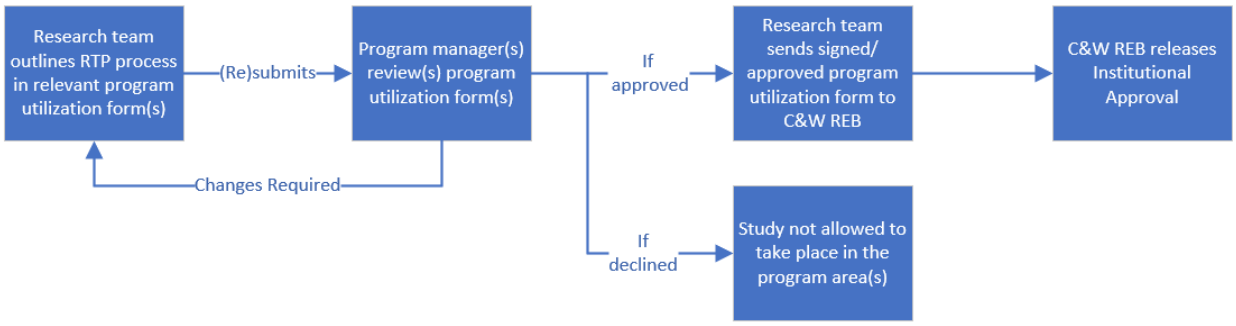
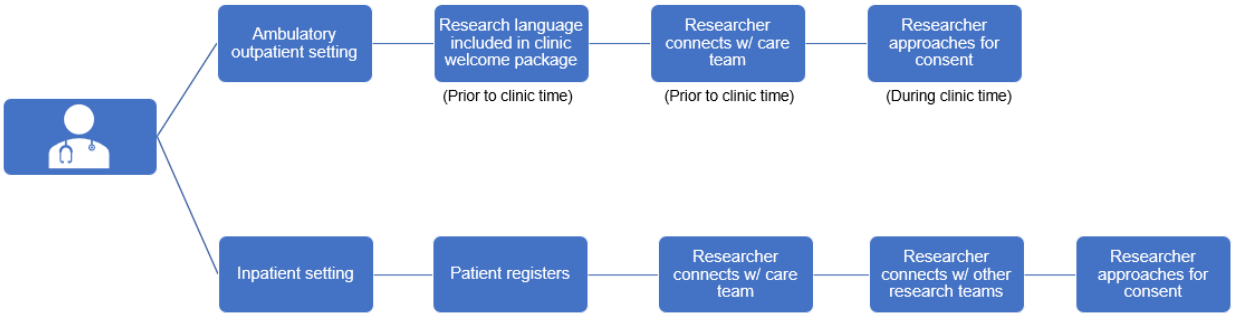
# Appendix A

*Institutional Approval Process*



# Appendix B

*Permissible RTP in-person recruitment Processes*




The intention of this document is an example and research teams should adapt this as appropriate in the unit/program/clinic.

# Appendix C

*Standard research language*

C) Research
wording in welcome

The intention of this document is an example and research teams should adapt this as appropriate in the unit/program/clinic.

# Appendix D

*Best practices on creating study poster & brochure*

D) Best Practices on
Creating Study Broc

The intention of this document is an example and research teams should adapt this as appropriate in the unit/program/clinic.

# Appendix E

*Letter of Initial Contact Template*

E) Letter of initial contact template 20

The intention of this document is an example and research teams should adapt this as appropriate in the unit/program/clinic.

# Appendix F

*Research Screening Log*

Screening Log.xls

The intention of this document is an example and research teams should adapt this as appropriate in the unit/program/clinic.

# Appendix G

*Example Recruitment Communication Log*

D) Research
Communication Log

The intention of this document is an example and research teams should adapt this as appropriate in the unit/program/clinic.

# Appendix H

*RA Research Decline Script*

H) RA Research
Decline Script.pdf

The intention of this document is an example and research teams should adapt this as appropriate in the unit/program/clinic.

# Appendix I

*Research Enrollment Log*

I) Enrollment Log 2025.04.14.xlsx

The intention of this document is an example and research teams should adapt this as appropriate in the unit/program/clinic.

# Appendix J

*REB Template Language*

J) In-Person
Recruitment Process

The intention of this document is an example and research teams should adapt this as appropriate in the unit/program/clinic.