Ontario Cancer Research Ethics Board
MaRS Centre, Suite 510 | 661 University Avenue
Toronto, Ontario | Canada M5G 0A3
416-673-6649 or 1-866-678-6427 ext. 6649 | www.ocreb.ca

Memo

To: Research community

From: OCREB

Date: November 12, 2025

RE: Pre-Screening Consents

From an ethical perspective, a study participant should sign the **main consent form** with all the study details, to ensure that there is an informed and voluntary decision around participation, knowing that there is the potential to be 'screened out' of the study once the screening procedures are completed.

However, pre-screening procedures can be used when it is necessary to identify participants whose tumour, tissue, or blood samples carry biomarkers or mutations required for clinical trial eligibility.

Pre-screening procedures are considered **research activities** and require **REB approval and informed consent**, even if the testing is conducted prior to main study enrollment. This document contains information to ensure ethical, privacy, and regulatory requirements are considered when participants' samples are tested before formal enrollment in a clinical trial.

The following OCREB guidelines on the use of a pre-screening consent in a research study must be followed when submitting a Pre-screening consent form as part of a clinical trial application:

i. The consent for pre-screening must be informed and voluntary, and must include all the required elements of consent: purpose, procedures, what is tested, risks, benefits (if any), alternatives, voluntariness, and contact information. The use of OCREB's pre-screening consent template is **mandatory**;

ii. The purpose of the pre-screening consent must be for the generation of information that is 'new' – i.e., not pre-existing (e.g., testing for a new biomarker); OR is testing for a biomarker that is not considered to be a standard test for the patient population of the main trial; OR the protocol requires central confirmation of already completed tests to be done at the Sponsor's designated laboratory;

iii. The information that will be generated is required to determine eligibility (not for eligibility);

iv. The prescreening consent should only be used for people who otherwise meet the study inclusion and exclusion criteria and who are likely candidates for participation in the main study;

v. The prescreening consent must not be used as a general screening tool to find people who have a biomarker or characteristic;

vi. The implementation of a pre-screening consent requires that the main consent also be provided to the participant (unsigned) to ensure that they are interested in participating in the main study before they consent to pre-screening;

vii. The sponsor must have incorporated the criteria and justification for the pre-screening consent in their protocol prior to its submission to OCREB i.e., the requirement is sponsor-driven to determine eligibility, and not added based on a participating site's request;

viii. If incidental or clinically actionable findings could be discovered, the pre-screening consent should include the plan for disclosure or non-disclosure of test results, as appropriate;

ix. Any other use of samples collected for pre-screening purposes i.e. future use/banking must be optional.

The Ontario Cancer Research Ethics Board operates in compliance with and is constituted in accordance with the requirements of: TCPS 2 of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans; the International Conference on Harmonization of Good Clinical Practices; Part C Division 5 of the Food and Drug Regulations of Health Canada; and the provisions of the Ontario Personal Health Information Protection Act 2004 and its applicable Regulations. OCREB is registered with the U.S. Department of Health & Human Service under the IRB registration number IRB00003960.

Jacqueline Limoges
Jacqueline Limoges (Nov 12, 2025 16:52:43 EST)

Jacqueline Limoges PhD RN
Chair, Ontario Cancer Research Ethics Board

References:

Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, Tri-Council Policy Statement; Ethical Conduct for Research Involving Humans (TCPS2)

ICH GCP International Council on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use – ICH Harmonised Tripartite Guideline – Guidelines for Good Clinical Practice E6(R3)

ICH GCP International Council on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use – ICH Harmonised Tripartite Guideline – Guideline on Genomic Sampling and Management of Genomic Data E18

Health Canada, Guidance Document: Part C, Division 5 of the Food and Drug Regulations "Drugs for Clinical Trials Involving Human Subjects" (Gui-0100)

U.S. Department of Health & Human Services, "Screening Tests Prior to Study Enrollment: Guidance for Institutional Review Boards and Clinical Investigators"; HHS-0910-1998-F-5158

Pre Screening Consents Guideline November 12, 2025

Final Audit Report 2025-11-12

Created:	2025-11-12
By:	Natascha Kozlowski (nkozlowski@oicr.on.ca)
Status:	Signed
Transaction ID:	CBJCHBCAABAAXYRlQT1OIaKEXnmN3zdB7SK3ZmQzwmln

"Pre Screening Consents Guideline November 12, 2025" History

Document created by Natascha Kozlowski (nkozlowski@oicr.on.ca)
2025-11-12 - 8:53:50 PM GMT

Document emailed to jlimoges@oicr.on.ca for signature
2025-11-12 - 8:53:55 PM GMT

Email viewed by jlimoges@oicr.on.ca
2025-11-12 - 9:50:01 PM GMT

Signer jlimoges@oicr.on.ca entered name at signing as Jacqueline Limoges
2025-11-12 - 9:52:41 PM GMT

Document e-signed by Jacqueline Limoges (jlimoges@oicr.on.ca)
Signature Date: 2025-11-12 - 9:52:43 PM GMT - Time Source: server

Agreement completed.
2025-11-12 - 9:52:43 PM GMT