Ontario Cancer Research Ethics Board
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Memo

To: Research community

From: OCREB

Date: June 15, 2022

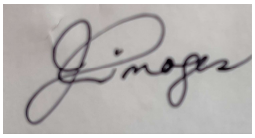
RE: Pre-Screening Consent Criteria

The OCREB policy related to the use of a pre-screening consent {PS ICF} in a research trial incorporates the following criteria:

- The consent for pre-screening must be informed and voluntary and must include all the required elements of consent;
- The rationale for the implementation of the consent must be study specific;
- 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 bio marker);
- The information that will be generated is required to determine eligibility (not for eligibility);
- The pre-screening consent has the potential to screen out a number of potential participants;
- The pre-screening consent should apply to all potential participants who are intending to enroll in the main study; and
- 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.
- In addition:
  The sponsor must have incorporated the criteria and justification for the pre-screening consent in their protocol prior to its submission to OCREB and to the participating centres – i.e., the requirement is sponsor driven to determine eligibility.

Note: Tumour testing for expediency, related to timelines that the sponsor has set, etc., generally does not meet the criteria for pre-screening. In these instances, OCREB requests that the sponsor extend/modify the timelines for the screening period to eliminate the need for pre-testing prior to other screening procedures.
From an ethical perspective, unless there is sufficient justification for a pre-screening consent, the participant should sign the main consent, 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 and during the study if required.

The Ontario Cancer Research Ethics Board operates in compliance with and is constituted in accordance with the requirements of: TCPS 2 - 2nd edition 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.



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