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 | https://ocreb.ca

Ontario Cancer Research Ethics Board N2/CAREB REB SOP Addendum

OCREB has adopted the N2/CAREB REB SOPs. However, in order to reflect specific OCREB requirements, this addendum must be used in tandem with the SOP noted below*.

N2/CAREB SOP 101 – Authority and Purpose

SOP Section	OCREB Addendum
5.1.1 The organization has authorized the REB to review research involving human participants conducted under the auspices of the organization;	**5.1.1** **The Ontario Institute for Cancer Research** has authorized **OCREB** to review research involving human participants conducted at institutions that have established a formal relationship with OCREB. • An institution must enter into a Participation Agreement with Clinical Trials Ontario (CTO) to use the online system. • An institution must register OCREB under its Federal Wide Assurance; • An institution authorizes OCREB to act as the REB of Record for research conducted under the auspices of the institution on a study-by-study basis; ○ A Satellite of an institution authorizes OCREB to act as the REB of Record for research conducted at the Satellite by executing an REB of Record Delegation Agreement;
5.4.1 The REB is established to review all research involving human participants within its established jurisdiction;	**5.4.1** **OCREB** is established to review all research involving human participants within its established jurisdiction **in accordance with the restrictions below:** (a) OCREB's mandate is restricted to multi-centre clinical trials, where multi-centre is defined as more than one participating Ontario centre using OCREB as the board of record, and clinical trial is defined as any research that prospectively assigns human participants to one or more health-related interventions to evaluate the effects on health outcomes; (b) OCREB will accept a study with only one confirmed participating centre, providing the sponsor is actively looking for and is confident that a second centre will agree to participate; (c) OCREB will accept the submission of all cooperative group (e.g., CCTG, NRG) multi-centre clinical trials even if a second centre has not been identified by the Provincial Applicant (PA) at the time of initial submission since cooperative group studies generally include more than one centre in Ontario; (d) Research that falls outside the scope of OCREB's mandate includes, but is not limited to, research that focuses on healthy volunteers or prisoners; observational studies; epidemiology research; retrospective chart reviews; emergency use of an investigational drug; planned emergency research; student-conducted research; and case studies. The PA or study sponsor should seek the opinion of OCREB if unsure about the applicability of a study to OCREB's mandate; (e) Exceptions may be made on a case-by-case basis. For example, for smaller institutions that do not have oncology expertise on their local REB, or for some early phase clinical trials when the later phase trials can be expected to be overseen by OCREB.

5.5 The REB shall apply the requirements of the applicable US regulations to the extent that they vary from the protections set out in the applicable Canadian regulations and guidelines.	**5.5** **OCREB** shall apply the requirements of the applicable US regulations to the extent that they vary from the protections set out in the applicable Canadian regulations and guidelines. **In situations of competing regulations, the highest applicable standard shall be applied.**

Revision History	
Date/Version	**Summary of Changes**
August 28, 2018/001	Original version.
December 4, 2019/002	5.1.1, OCREB Addendum, 3rd bullet: removed reference to the REB of Record Agreement.
March 21, 2025/004	5.1.1, OCERB Addendum, 1st bullet: clarified the need for an REB of Record Agreement; 5.1.1, Replaced "Participating Organization" with "Institution" and clarified "**An Institution** must enter into a Participation Agreement with Clinical Trials Ontario (CTO) **to use the online system.**" 5.4.1 (a), Clarification added 5.5, Added guidance for instances where multiple regulations apply.