Ontario Cancer Research Ethics Board
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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 **Participating Organizations**; • A Participating Organization must enter into a Participation Agreement with Clinical Trials Ontario (CTO); • A Participating Organization must register OCREB under its Federal Wide Assurance; • A Participating Organization authorizes OCREB to act as the REB of Record for research conducted under the auspices of the Participating Organization, by executing an REB of Record Agreement on a study-by-study basis; ○ A Satellite of a Participating Organization authorizes OCREB to act as the REB of Record for research conducted at the Satellite by executing a one-time 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, 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;

Revision History	
Date/Version	**Summary of Changes**
August 28, 2018/001	Original version.