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 Glossary of Terms

SOP Section	OCREB Addendum
N/A	**Assent:** is the affirmative agreement of someone not capable of giving consent to participate in an activity such as research. Mere failure to object should not be construed as assent. Research with children or adults not capable of giving consent requires the consent of the parent or legal guardian, and the assent of the potential research participant.
N/A	**Designated Satellite Investigator** (**DSI)**: is a physician at a Satellite who is designated as the leader of the research activities at the Satellite.
N/A	**Mature minor:** a young individual who demonstrates adequate understanding and decision-making capacity to choose his/her treatment, including consenting to participate in research.
N/A	**Participating Organization:** an institution that has signed a Participation Agreement with Clinical Trials Ontario and has registered OCREB under its Federal Wide Assurance. The Participating Organization may delegate to OCREB on a study-by-study basis by executing an REB of Record Agreement.
N/A	**Pre-approved administrative changes:** all provincially approved OCREB study documents (including participant materials such as wallet cards and consent forms), are pre-approved for use by all participating centres, with the application of administrative changes. The provincially approved document version date must be maintained despite the administrative changes. Refer to the OCREB Guidance for pre-approved administrative changes for more details.
N/A	**Provincial Applicant (PA):** the individual who takes responsibility for submitting the initial and ongoing study-wide (provincial) materials to OCREB on behalf of the participating centres. This includes the provincial initial application (PIA), and all post-approval provincial applications. A Principle Investigator (PI) at one of the participating centres generally assumes the role of PA.

N/A	**Reportable event:** includes events occurring during the course of the study or after study completion that could significantly impact the safety and welfare of currently or previously enrolled study participants and thus may impact ongoing REB approval of the study. Reportable events that meet the REB reporting requirements are submitted at the provincial or at the centre level, as applicable:
	• **Provincial**
	  ○ DSMB/C Report
	  ○ Interim Analysis Results
	  ○ Safety Notice/Update
	  ○ Periodic External (Non-Local) AE/SUSAR Summary Report
	  ○ Single External (Non-Local) Adverse Event Report
	  ○ Other Reportable Event (specify)
	• **Centre**
	  ○ Local (Internal) Serious Adverse Event (SAE)
	  ○ Protocol Deviation/Violation
	  ○ Privacy Breach
	  ○ Audit/Inspection Report
	  ○ Study Participant Complaint

Researcher: the leader of a research team who is responsible for the	**Researcher:** the leader of a research team who is responsible for the conduct of the research, and for the actions of any member of the research team. (Also known as "Qualified Investigator"). For the purposes of the single REB/multi-centre model, **the researcher who takes the lead on submitting the study-wide/provincial applications is**

SOP Section	OCREB Addendum
conduct of the research, and for the actions of any member of the research team. (Also known as "Qualified Investigator").	**referred to as the Provincial Applicant. The researcher at the Participating Organization also is referred to as the Centre Principle Investigator (PI) or Centre PI.**
N/A	**Satellite:** is a distinct physical location that has entered into a Research Agreement with a Participating Organization to allow the Satellite to engage in research under the direction and oversight of the Participating Organization. The Satellite will assign a Designated Satellite Investigator.

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