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 403 – Initial Review - Criteria for REB Approval

SOP Section	OCREB Addendum
5.0 PROCEDURE (paragraph 2) Following initial review of the research, the REB should be prepared to make a determination as to the approvability of the research.	**5.0 PROCEDURE (paragraph 2)** Following initial review of the research, the REB should be prepared to make a determination as to the approvability of the research. **In the single REB/multi-centre model, initial REB approval involves the approval of a provincial initial application from a lead or provincial applicant (PA), as well as a centre initial application (CIA) from each participating centre.**
5.1 Minimal Criteria for Approval of Research In order for the research to receive REB approval, the REB will take the following into consideration, **5.1.1** The application has been signed by the Researcher and, if applicable, by a designated Organizational Official, indicating that the Researcher has the qualifications to conduct the research, **5.1.2** Any potential conflicts of interest are declared and are managed appropriately to prevent any compromises to the safety or well-being of the participants or to the integrity of the data, **5.1.19** If applicable, the research has been or will be registered via an internationally recognized clinical trial registry **and a registration number has been/will be submitted to the REB. If the research is not yet registered, the researcher shall provide the REB with the registration number upon registration**.	**5.1 Minimal Criteria for Approval of Research, also called the Provincial Initial Application (PIA)** In order for the research to receive REB approval, the REB will take the following into consideration (refer also to the Reviewer Guidelines, Forms and Criteria for Approval): **5.1.1** **Before assigning a new study/PIA to a CTO Qualified REB, CTO personnel screen the PIA to ensure that the study meets the CTO mandate, that the appropriate institutional representative is listed in the application, and to confirm that the PA has signed the application**; **5.1.2** Any potential conflicts of interest **at the provincial level** are declared and are managed appropriately to prevent any compromises to the safety or well-being of the participants or to the integrity of the data; **5.1.19** If applicable, **the PA confirms that** the research has been or will be registered via an internationally recognized clinical trial registry.
5.2 Additional Criteria New subsection	**5.2 Additional Criteria** **5.2.3 Minimal Criteria for Approval of a Centre to Conduct the Approved Research:** After the REB has granted provincial approval of a study, each participating centre must submit an abbreviated centre initial application (CIA) for approval to conduct the research. In order for the centre to receive REB approval, the REB will take the following into consideration (refer also to the Reviewer Guidelines, Forms and Criteria for Approval): • Before forwarding the CIA to the REB of Record, CTO personnel screen the application to confirm that the institutional requirements have been met (as applicable), to ensure that the appropriate institutional representative

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	is included in the application, and to confirm that the PI, a department approver and the institutional representative have signed the CIA; • Any potential conflicts of interest are declared and are managed appropriately to prevent any compromises to the safety or well-being of the participants or to the integrity of the data; • The recruitment methods respect the privacy of individual participants and conform to the privacy regulations; • The informed consent process will be appropriately documented as required by applicable regulations and guidelines; • There are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data; • Participating centres will adopt the expiry date of the overall study, regardless of when the CIA is approved. **NOTE.** To facilitate compliance with OCREB's long-standing controlled honour-system for the implementation of consent forms at the centre, and to present consistent information to all study participants in Ontario, each centre must adopt the OCREB approved provincial consent forms with the addition of the authorized pre-approved administrative changes only. Centres are not required to submit their centre consent forms to OCREB. OCREB does not review centre consent forms. Refer to the "*Guidance for pre-approved administrative changes*" on the OCREB website for details.

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