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 404 – Ongoing REB Review Activities

SOP Section	OCREB Addendum
5.1.1 The Researcher is responsible for submitting to the REB any changes to the approved research in the form of an amendment. Changes to the approved research include modifications including (for example) modifications to the research, to the consent form, to the Investigator Brochure (IB) or product monograph (PM), changes in participant materials (e.g., wallet cards, diary cards, recruitment materials), a change in the Researcher etc.;	**5.1.1** **Provincial Amendments** The **Provincial Applicant (PA)** is responsible for submitting to the REB any **study-wide/provincial** changes to the approved research in the form of a **provincial** amendment **(PAM)**. **This** includes modifications to the **protocol**, to the consent form, to the Investigator Brochure (IB) or product monograph (PM); changes in participant materials (e.g., wallet cards, diary cards, recruitment materials); a change in PA, etc. **OCREB approved participating centres do not submit a separate application to implement a PAM. The approved PAM and associated study documents (including participant materials such as wallet cards and consent forms), are approved for use by all centres.** **Additionally:** **Centre Amendments** The Centre PI is responsible for submitting to the REB any centre-specific changes to the approved research in the form of a centre amendment (CAM). This includes modifications to the approved centre-specific participant materials, translation of approved materials at the centre level, or a change in the Centre PI. **NOTE.** Administrative amendments such as spelling corrections or changes in study personnel (with the exception of the PA and Centre PI), and replacement of an incorrect document (providing the correct document has been reviewed and approved) may be processed and acknowledged by the REB Office Personnel.
5.1.2 When the amendment includes a change to the consent form, the Researcher must indicate his/her recommendation for the provision of the new information to current and/or past research participants;	**5.1.2** When the amendment includes a change to the consent form, the **PA** must indicate his/her recommendation for the provision of the new information to current and/or past research participants, **and whether the participant's signature is recommended**. **Additionally:** • A revised main consent form is required if the study is open to enrolment at any of the participating centres; • A consent update form containing only the new information is required if there are any currently enrolled participants on active treatment or in follow-up at any of the centres, or for completed participants if the study is closed to follow-up but the new findings might affect the

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	long term health or welfare of the participant; • If the study is closed to enrolment, a revised main consent form is not required. A consent update form is required if the new findings might affect the long term health or welfare of the participant; • Refer also to the Guidelines for Providing New Information.
5.2.1 The Researcher is responsible for submitting reportable events that meet the REB's reporting criteria according to the local procedures;	**5.2.1** **Provincial Reportable Events** • The **Provincial Applicant (PA)** is responsible for submitting **all provincial** reportable events **(PRE)** that meet the REB's reporting criteria, **as per the CTO PRE application form**. **Additionally:** • PRE include DSMB/C reports, interim analysis results, safety notices/updates, non-local (external) adverse event reports, other events that suggest that the research puts participants at greater risk of harm than previously known or recognized; **Centre Reportable Events** • The Centre PI is responsible for submitting all centre reportable events (CRE) that meet the REB's reporting criteria, as per the CTO CRE application form. CRE may include: local adverse events; protocol deviations/violations, privacy breaches; audit or inspection findings; participant complaints; • Refer also to the Guidelines for Protocol Deviation Reporting
5.2.2 Local AEs: The Researcher must report the following to the REB in a timely manner: • Any local adverse event that in the opinion of the Researcher meets the definition of an unanticipated problem, • All reports submitted to the REB must have all research participant identifiers removed (i.e., participant research number only), • Once a local SAE is acknowledged by the REB, subsequent important follow-up reports related to the SAE should be submitted when relevant information is available, as SAE update(s)**. All initial and subsequent follow-up reports will be retained with the reportable event**;	**5.2.2** Local AEs **that meet the reporting criteria**: The **Centre PI** must report the following to the REB in a timely manner: • Any local adverse event that in the opinion of the **Centre PI** meets the definition of an unanticipated problem **(i.e., is unexpected AND related or possibly related to participation in the research AND suggests that the research places research participants or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized;** • All reports submitted to the REB must have all research participant identifiers removed (i.e., participant research number only); • Once a local **AE** is acknowledged by the REB, subsequent important follow-up reports related to the **AE** should be submitted when relevant information is available, as **Reportable Event updates**;

Revision History	
Date/Version	**Summary of Changes**
August 28, 2018/001	Original version.
December 4, 2019/002	5.2.2 SOP Section: revised to reflect N2/CAREB REB SOP v3 5.2.2 OCREB Addendum : revised for consistency with N2/CAREB REB SOP v3