Sunnybrook
HEALTH SCIENCES CENTRE

## Sunnybrook REB Standard Operating Procedure Addendum

The Sunnybrook REB has adopted the N2/CAREB REB SOPs and in order to reflect specific Sunnybrook REB requirements, this addendum complements the N2/CAREB REB SOP noted below.

## N2/CAREB REB SOP:
## # 404 – Ongoing REB Review Activities

| N2/CAREB REB SOP | Sunnybrook REB SOP Addendum |
|---|---|
| **5.2.2**<br>**Local AE's:** The Researcher must report the following to the REB in a timely manner. | • All local adverse events (AEs) that in the opinion of the Researcher meet the following criteria must be submitted to the REB:<br>○ Serious AND<br>○ Unexpected (nature, severity, frequency) AND<br>○ Related or possibly related to participation in the research? AND<br>○ Suggests that the research places participants or others at a greater risk of harm than was previously known or recognized?<br><br>• AE's that meet the above criteria must be submitted to the REB within<br>○ **15 calendar days** of the Researcher becoming aware of the event.<br>○ Fatal or life-threatening local AE's should be reported to the REB within **7 calendar days.**<br><br>• Follow-up reports should be submitted to the REB when there is new relevant information. It is the responsibility of the Researcher to ensure *subsequent* and *final* report(s) are submitted.<br><br>• If the study action recommended (as indicated on the form) requires any changes to the study, submit relevant documents under separate submission as an amendment to the REB<br><br>• The REB procedure for reporting supersedes any other time frame specified in a research protocol. |
| **5.2.3**<br>**Non-Local (External) Adverse Events:** Upon receipt of an external adverse event (EAE) or a periodic safety update or safety summary report, the Researcher must | • Non-local adverse event (AE) reports are reportable to the **Sunnybrook REB**, if in the opinion of the Researcher,<br>○ it meets the definition of an **unanticipated problem** |

| | |
|---|---|
| determine if it meets the REB reporting criteria: | ○ **AND** requires a **change to the research** and/or informed consent form and/or requires immediate notification to the participant for safety reasons.<br>○ **AND** is considered **serious**<br>▪ results in death,<br>▪ is life-threatening,<br>▪ requires inpatient hospitalization or prolongation of existing hospitalization,<br>▪ results in persistent or significant disability/incapacity, or<br>▪ is a congenital anomaly/defect.<br><br>• The sponsor and/or Researcher shall notify the REB when the reported information is considered to affect the rights and welfare of research participants, and the recommended actions to follow.<br><br>• All previous safety reports concerning similar events and analysis of the significance of the current event in light of the previous reports may be requested by the REB.<br><br>• Through review of the new information, the REB may require that the research be further modified, suspended or terminated.<br><br>• The REB will consider if this new information should be communicated to research participants.<br><br>• If the REB receives reports that do not meet the submission criteria, the REB reserves the right to return such reports, without review, to the Researcher. |
| **5.2.5**<br>Deviations must be reported within a time frame specified by the REB; deviations that lead to an SAE should be reported within a time frame specified by the REB; | • A deviation (see 'protocol deviation' in glossary) should be reported as soon as the Researcher becomes aware of the deviation. |

| Revision History | |
|---|---|
| **Effective Date** | **Summary of Changes** |
| March 1, 2018 | Original version |
| July 13, 2021 | -References to old REB forms deleted.<br>-Revised AE criteria to clarify which AEs are reportable to the REB (for consistency with the SunRISE reportable event form)<br>-Delete reference to REB acknowledgement of AEs |
| December 12, 2023 | No revisions needed |

This N2/CAREB REB SOP addendum has been reviewed and approved for use by:

Keri Durrant

Keri Durrant (Nov 29, 2023 08:22 EST)

Keri Durrant
Director, Human Research Protections Program

Brian J Murray (Nov 28, 2023 20:46 EST)

Dr. Brian J. Murray
Chair, Sunnybrook Research Ethics Board