Bloorview RESEARCH INSTITUTE

Holland Bloorview Kids Rehabilitation Hospital

Research Ethics Board Standard Operating Procedure Addendum

The Holland Bloorview Research Ethics Board (HB REB) has adopted the N2/CAREB REB SOPs. Some internal practice requirements differ from those in the N2/CAREB SOPs. This SOP addendum describes the specific HB REB requirements related to the N2/CAREB SOP noted below.

SOP #	Title
404.003	Ongoing REB Review Activities

N2/CAREB REB SOP Section #	HB REB SOP Addendum
5.2 Reportable Events 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,	5.2.2 replace by: All Local Adverse Events (AEs) that in the opinion of the Researcher meets the definition of an unanticipated problem must be reported to the REB with the information available at the time within: • 15 calendar days of the Researcher becoming aware of them All local AEs that are considered Serious Adverse Events (SAEs) and in the opinion of the Researcher meets the definition of an unanticipated problem must be reported to the REB with the information available at the time within: • 7 calendar days of the Researcher becoming aware of them It is the Researchers responsibility to submit subsequent and final Follow-up reports to the REB when further information is obtained. If the action recommended requires any changes to the study, the Researcher must submit an Amendment in the eREB system.
5.2.3 Non-Local (External) Adverse Events: Upon receipt of an external adverse event (EAE) or a periodic safety update or safety summary report,	5.2.3 Replace by: Non-local AEs (including periodic safety update or safety summary report), must be reported to the REB if they, in the opinion of the Researcher,

the Researcher must determine if it meets the REB reporting criteria: • Non-local adverse event reports are reportable to the REB, if in the opinion of the Researcher, it meets the definition of an unanticipated problem AND requires a change to the research and/or informed consent form and/or requires immediate notification to participants for safety reasons, • The individual AE reports or periodic safety updates or safety summary reports that meet the reporting criteria must be submitted to the REB in a timely manner;	meet the definition of an unanticipated problem AND: • Require a change to the research and/or informed consent form and/or requires immediate notification to participants for safety reasons, • Are considered an SAE Non-local AEs that meet the criteria above must be submitted to the REB within 15 calendar days of the research becoming aware of them
5.2.5 Deviations to Previously Approved Research: The Researcher must report to the REB any deviations that meet the following reporting criteria: • Deviations that in the opinion of the Researcher jeopardize the safety of research participants, or that jeopardize the research efficacy or data integrity, • Any sponsor-approved waivers to the participant eligibility criteria, • Any change in the approved process for obtaining consent (e.g., improper translation, current ICF not implemented), • Any deviations that lead to an SAE, • Deviations must be reported within a time frame specified by the REB; deviations that lead to an SAE should be reported with a timely manner;	5.2.5 Replace by: Deviations to previously approved research include unanticipated or unintentional changes and in addition to the criteria in the 5.2.5 must also be reported to the REB if they: • Eliminate an immediate hazard(s) to participants or other, • Compromise the privacy of research participants, confidentiality of data. Research deviations that eliminate an immediate hazard, jeopardize the safety of research participants or lead to an SAE must be reported to the REB within: • 7 calendar days of the Researcher becoming aware of them All other Deviations must be submitted to the REB within: • 15 calendar days of the Researcher becoming aware of them *See Glossary of terms for definitions.

Revision History	
Version Date	Summary of Changes
February 13, 2023	5.2.2 and 5.2.3 - Revision/clarification of reporting criteria and timelines to align with CAREB guidance and Health Canada requirements 5.2.5 - Revision of timelines to align with CAREB guidance and Health Canada requirements. - Clarification that all research deviations need to be reported to the REB
October 23, 2020	Original Version
This N2/CAREB REB SOP Addendum has been reviewed and approved for use by the HB REB	