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,	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 within: • 7 days of the Researcher becoming aware of them All local AES that are considered Serious Adverse Events (SAEs) must be reported to the REB within: • 3 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 there is new relevant information. If the study action recommended requires any changes to the study, the Researcher must submit an Amendment request.
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, 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	Non-local AEs must be reported to the REB if they, in the opinion of the Researcher, 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

• change to the research and/or informed consent form and/or requires immediate notification to participants for safety reasons,	Non-local AEs that meet the criteria above must be submitted to the REB within 3 days of the research becoming aware of them
• 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;	All periodic safety updates or safety summary reports must be submitted to the REB in a timely manner. Reports not meeting these requirements will be returned to the submitter with a description of the REB reporting requirements.
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;	Protocol deviations include unanticipated or unintentional protocol 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. Protocol deviations that eliminate an immediate hazard, jeopardize the safety of research participants or lead to an SAE must be reported to the REB within: • 5 days of the Researcher becoming aware of them All other Protocol Deviations must be submitted to the REB within: • 15 days of the Researcher becoming aware of them *See Glossary of terms for definitions.

Revision History	
Version Date	Summary of Changes
October 23, 2020	Original Version
This N2/CAREB REB SOP Addendum has been reviewed and approved for use by the HB REB	