

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
303.003	Document Management

N2/CAREB REB SOP Section #	HB REB SOP Addendum
5.3 – Document Access, Storage and Archiving 5.3.2 The REB records are housed securely with back-up, disaster and recovery systems in place.	HB REB documents are housed securely both in paper and electronic format. Original paper documents do not have a back-up, disaster and recovery system in place.
5.4 – Confidentiality and Document Destruction 5.4.4 The REB will retain required records (e.g., research-related or REB administrative documents, as applicable) for a minimum of 3 years after completion/termination of the trial, or for the maximum amount of time stipulated in any applicable governing regulation(s) e.g., 25 years for Health Canada regulated research;	The HB REB will retain required records for 7 years after the research study is closed or terminated for non-regulated research, or for the maximum amount of time stipulated in any applicable governing regulations.

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	