

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
303.004	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.	5.3.2 Replace by 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. As of September 2020 all HB REB documents are securely saved on the eREB system in an electronic format until the end of the required retention period.
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;	5.4.4 Replace by 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
February 13, 2023	5.3.2 Editorial change to better reflect HB REB practices.
June 26, 2023	Updated version number to be in line with revised N2 CAREB SOP
This N2/CAREB REB SOP Addendum has been reviewed and approved for use by the HB REB	