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
303.005	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);	 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.
5.5 Use of Electronic and Cloud-Based Application and Document Management Systems 5.5.1 Institutions are responsible for ensuring that any electronic or cloud-based systems used to create, store, manage, or archive REB records are fit for purpose and support the integrity, confidentiality, reliability, and accessibility of those records throughout their lifecycle; 5.5.2 Systems used for REB document management must be implemented and maintained in a manner consistent with applicable regulatory, ethical, and privacy requirements, including, where applicable, US FDA 21 CFR Part	

11 (Electronic Records and Electronic Signatures), federal and provincial privacy legislation, and institutional information security policies; 5.5.3 Electronic systems must support the accuracy, completeness, and retrievability of REB records such that a complete history of REB review, decision-making, approvals, amendments, and archival actions can be reconstructed and made available for inspection, audit, or regulatory review as required; 5.5.4 Institutions must ensure that access to electronic REB systems is controlled and appropriate to users' roles and responsibilities, and that responsibilities for system administration, oversight, and record management are clearly defined; 5.5.5 Where audit trails or system logs are used, they must be retained and made available in accordance with applicable regulatory and institutional requirements; 5.5.6 Where REB records are stored or processed using cloud-based services, institutions are responsible for ensuring that data handling practices comply with applicable jurisdictional privacy requirements and that arrangements are in place to protect confidentiality, security, and regulatory access; 5.5.7 Institutions must have processes to ensure the continuity, retention, and accessibility of REB records in the event of system upgrades, migrations, vendor changes, or system decommissioning.	

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
July 13, 2026	Updated 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	