

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
406.003	Research Completion

N2/CAREB REB SOP Section #	HB REB SOP Addendum
<p>5.1 Determining when Research can be Closed</p> <p>5.1.1 The Researcher may submit a research closure report to the REB when there is no further participant involvement at the site, all new data collection is complete, and the sponsor closeout activities, if applicable, have been completed;</p>	<p><i>In addition to the criteria in 5.1.1, Researchers may not submit a Study Closure report until:</i></p> <ul style="list-style-type: none"> • <i>All data clarification/correction is complete.</i> • <i>All data transfer is complete.</i> • <i>All access to PII/PHI (e.g. participants' medical records) is complete.</i> <p>Administrative Study Closure by the REB</p> <p>When REB approval has expired, the eREB system will send an Expiry/On-Hold Notice to the Researcher.</p> <p>The Researcher must promptly submit a Continuing Review Application or a Study Closure report.</p> <p>If the Researcher has not submitted a Continuing Review Application or a Study Closure report within 90 days after the expiry date, the study will be closed.</p> <p>A Study Closure Notification Letter signed by the REB Chair or their designate will be sent to the Researcher to notify them of the study closure and closure of the REB file.</p> <p>Alternatively, an administrative study closure letter may also be sent if the institution notifies the REB that the study is unable to be conducted</p>

	<p>or continued at Holland Bloorview. This may include but not be limited to administrative, logistical or legal complications. At that time, the REB Chair or their designate will be consulted to determine next steps. Prior to issuing an administrative study closure letter, the REB will consider:</p> <ul style="list-style-type: none"> - Risk to current participants - Actions to protect the safety, rights and well-being of currently enrolled participants, - The appropriate care and monitoring of research participants, - Whether withdrawal of enrolled participants is warranted and the specific procedures for their safe withdrawal, - Whether participants should be informed of the closure - Whether adverse events or outcomes should be reported to the REB <p>Once the REB Chair or designee has made the determination it is appropriate to close the study, a Study Closure Notification Letter signed by the REB Chair or their designate will be sent to the Research and the institutional official to notify them of the study closure and the reasons for the decision</p>
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Revision History	
Version Date	Summary of Changes
December 12, 2022	Revision to criteria stating when a Study Closure report can be submitted Addition of instance when an Administrative Study Closure may be sent
	Original Version
This N2/CAREB REB SOP Addendum has been reviewed and approved for use by the HB REB	