

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>In addition to the criteria in 5.1.1, Researchers may not submit a Study Closure report until:</p> <ul style="list-style-type: none"> • All data have been analyzed, • The objectives of the approved study are met to the extent possible, • All letters of appreciation and lay summaries of findings are shared with participants (with few exceptions). <p>Industry sponsored clinical trials shall be reported as completed or terminated promptly following the sponsor's and the LPI's close-out activities at that clinical trial site. A copy of the official "close-out letter" will be sent to the REB together with applicable details that address the above.</p> <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 within 14 days of the date of notification.</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>

	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.
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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	