

## 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             |
|---------|-------------------|
| 405.005 | Continuing Review |

| N2/CAREB REB SOP Section #                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | HB REB SOP Addendum                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
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| <p><i>5.1 Continuing Review by the Full Board</i></p> <p>5.1.2 At a minimum, the REB requires that an application for continuing review be submitted once per year until all of the data has been collected, all contact with research Participants has concluded and the closure of the research has been acknowledged by the REB;</p> <p>5.1.5 To assist the Researchers in submitting on time, a courtesy reminder(s) prior to the expiry date may be generated;</p> <p><i>5.4 Continuing Review Applications not Received by the Expiry Date</i></p> <p>5.4.1 If an application for continuing review is not submitted by the expiry date, a warning or suspension notice will be issued to the Researcher. When suspended, the Researcher must suspend all research activities as specified by the REB. The responsible REB Office Personnel will follow-up with the Researcher to ensure that the application for continuing review is submitted as soon as possible;</p> | <p>In addition to the criteria in 5.1.2, Researchers must continue to submit applications for continuing review until:</p> <ul style="list-style-type: none"> <li>• <i>All data clarification/correction is complete.</i></li> <li>• <i>All data transfer is complete.</i></li> <li>• <i>All access to PII/PHI (e.g. participants' medical records) is complete.</i></li> </ul> <p>5.1.5 Replace by: To assist the researchers in submitting on time, the eREB system will send Continuing Review reminders to the Researcher prior to the expiry date.</p> <p>5.4.1 Replace by:<br/>The REB Office Personnel will send an Expiry/On-Hold Notice through the eREB system once the REB becomes aware the study has expired. Once placed on Hold, the Researcher must suspend all research activities as specified by the REB.</p> <p>On Hold notices are copied to the Research Ethics, Research Operations, Grants, Contracts and Awards, and Research Finance Offices.</p> |

| Revision History                                                                    |                                                                                                                                                                                                                                                                                                      |
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| Version Date                                                                        | Summary of Changes                                                                                                                                                                                                                                                                                   |
| October 23, 2020                                                                    | Original Version                                                                                                                                                                                                                                                                                     |
| December 12, 2022                                                                   | 5.1.2 Revision to criteria stating when a continuing review is required<br>5.1.4 Removal of section to revert back to original wording in N2/CAREB SOP<br>5.1.5 Removal of timelines that state when a system generated reminder is sent<br>5.4.1 Editorial change to better reflect HB REB practice |
| 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 |                                                                                                                                                                                                                                                                                                      |