Ottawa Health Science Network Research Ethics Board (OHSN-REB) /
Conseil d'éthique de la recherche du réseau de science de la santé d'Ottawa (CÉR-RSSO)
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OHSN-REB Standard Operating Procedure Addendum

Rationale: The OHSN-REB is a member of the Canadian Association of Research Ethics Boards (CAREB), and as approved by the OHSN-REB Executive Committee, has adopted the N2 - CAREB SOPs. To reflect specific OHSN-REB requirements, this addendum complements the N2- CAREB SOP noted below.

N2/CAREB SOP: # 405 – Continuing Review

N2-CAREB SOP Guidelines	OHSN-REB Standard Operating Procedure Addendum
5.3 REB Determinations 3.2: The REB may also make additional determinations, including: • Request changes to the informed consent form(s), • Request changes for the continuing review interval (based on risks), • Impose special precautions (e.g., frequency of monitoring, the requirement for interim reports or duration of approval period), • Require modifications to the research, • Suspend or terminate REB approval.	If participant recruitment is ongoing at the time of the continuing review and no changes have been made to the consent form in the last 5 years, the REB will assess the consent form to determine if updates are necessary to align with current guidelines, regulations and consent templates if applicable to the study. If an update is required, the applicant will be instructed to submit an amendment form to update the consent form using the most current template.
5.4 Continuing Review Applications Not Received by the Expiry Date 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.	**Investigator and Study Team Management of Study Expiry** • The home page of the investigator's Integrated Research Information System (IRIS) features a built-in notification system called the "Ethics Ticker." • The Ethics Ticker displays all studies that the investigator has, with expiration dates set for "90," "60," and "40" days, as well as any protocols that have recently expired. The Ethics Ticker serves as the investigator's notification that a study's ethical approval is nearing expiration. Additionally, the investigator is automatically notified via email 60 days and again 45 days before the study expires and again on the day of expiration. It is the researcher's responsibility to regularly check the Ethics Ticker, document the expiry dates and reminders in their Outlook calendars, and submit the continuing review form 40 to 50 days in advance of the expiration to allow sufficient time for review, especially for studies requiring full board review.

	REB Process for Study Expiry • An automated email from REBAdministration@ohri.ca is sent to the principal investigator and study team informing them that the study has expired. • The REB office follows up with a reminder email, informing the study team that a continuing review form or study closure form is required within 5 business days. • The researcher must suspend all research activities as specified by the REB but may continue research-related medical treatment/intervention to protect the rights, safety, and welfare of current research participants. The REB must be immediately notified of this activity. • If study activity took place during the lapse in ethics approval, the study team may be required to submit a privacy breach reportable event and must consult with the REB office. ➢ The Chair or Vice-Chair will review the activity that took place during the lapse and determine if any action is required. For example, if data was collected during the lapse, the Chair or Vice-Chair may determine that the data cannot be used. • If no response is received from the investigator or study team by business day 10, the REB may close the REB file and mark it as abandoned. Additionally, the REB office will inform the contracts and grants office, as applicable.
5.4.3 The Researcher must document the reasons for the lapse and identify the steps taken to prevent future lapses;	In the local REB application, the continuing review form and the privacy breach reportable event form include questions addressing the study lapse (e.g., a detailed explanation for the lapse in approval and a corrective action plan (CAPA) to prevent future lapses). Repeat offenders will be required to meet with the Chair and/or Vice-Chair of the REB.

Revision History

Version Number	Effective Date	Summary of Changes
Version 3	April 30, 2025	Administrative updates and updates to the study expiry process.
N/A	September 29, 2023	No revisions required to addendum N2 CAREB SOP version 405.004
Version 2	January 12, 2022	Administrative changes (logos, rationale, etc.); addition of Section 5.3.
Version 1	September 2, 2015	Initial Version

This N2-CAREB SOP Addendum has been reviewed and approved by the OHSN-REB Administrative Committee.