

**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 Operations 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: # 108 – Standard Operating Procedure Maintenance

N2-CAREB SOP Guidelines	OHSN-REB Standard Operating Procedure Addendum
1.0 Purpose	This OHSN-REB Addendum describes the process for the development, review, approval, and maintenance of written OHSN-REB addendums intended for use by OHSN-REB personnel and all applicants submitting to OHSN-REB. The OHSN-REB addendums are prepared and distributed by the REB Office.
2.0 Scope	OHSN-REB addendums are an extension of approved N2 CAREB SOPs. In addition to reflecting OHSN-REB requirements and recommendations related to a N2 - CAREB SOP, they provide further information and clarification to sections within individual SOPs, and links to resources where applicable.
3.0 Responsibilities	The OHSN-REB is responsible for developing and maintaining the OHSN-REB addendums.
5.1 Development, Review, Revision and Approval of Policies & Procedures 5.1.1 The qualified REB Office Personnel will review the SOPs at least biennially. Applicable SOPs will be reviewed sooner if changes to regulations, guidelines, or standard practice warrant revisions or the creation of new SOPs; 5.1.2 SOPs may be revised for reasons including, but not limited to: changes to regulations or guidelines, new policies, or changes to REB or administrative practices; 5.1.3 The qualified REB Office Personnel will make the necessary modifications to existing SOPs or draft a new SOP(s). SOPs are controlled documents and new drafts will be indicated by the addition of “DRAFT version date” and removal of the previous “Final Version Date”; 5.1.4 The revised SOP(s) will be circulated to the REB Office Personnel and REB Chair or designee, as well as REB members (as appropriate) for review. Comments	<ul style="list-style-type: none"> • The standard format for OHSN-REB Addendums will be used. Addendum content will reference the N2 CAREB SOP section(s). • Addendums will be version controlled, as described in N2 CAREB SOP108. • The effective date refers to the date that the addendum was adopted by the OHSN-REB. For minor changes, the effective date will remain the same as the last major revision. • Addendums will be created or updated, as needed, to reflect any changes to regulations, guidelines, research practice, or institutional policies. • Addenda will be reviewed at minimum every 2 years, in keeping with Section 5.1.1 of SOP 108. • As the Operations Committee has authorized the REB Administrative Committee to review and approve the N2 CAREB SOPs, the timeline for on-going review of the main SOPs will be linked to and rely upon the N2 review cycle.

<p>will be incorporated into a new version with an updated version date;</p> <p>5.1.5 Once the SOP content is approved, the draft version date will be removed, and the date of the approved version will be entered as the “Final Version Date”. The history of revisions will be recorded in the ‘SOP History’ section of each SOP;</p> <p>5.1.6 Signatures on the SOP as determined by organizational policy will denote SOP approval. A new final version of the SOP supersedes any previous versions.</p>	<ul style="list-style-type: none"> • For each revision, a summary of changes and the effective date will be included at the end of the addendum. • The Operations Committee has authorized the REB Administrative Committee to review and approve the N2 CAREB SOPs and OHSN-REB prepared addendums to the SOPs.
<p>5.2 Distribution and Communication</p> <p>5.2.1 New or revised SOPs and associated guidance documents will be communicated and disseminated to all individuals identified in the ‘Responsibilities’ section of each SOP;</p> <p>5.2.2 The SOPs will be available to Researchers and researcher sites, Sponsors and Regulatory Authorities as required;</p> <p>5.2.3 Qualified REB Office Personnel will train members of the REB and the REB Office Personnel on any new or revised policy and or relevant procedure, as applicable;</p> <p>5.2.4 Each new REB member must review the applicable policies and procedures prior to undertaking his/her responsibilities as an REB member;</p> <p>5.2.5 Each new REB Office Personnel must review the applicable policies and procedures prior to undertaking his/her responsibilities with the REB office;</p> <p>5.2.6 Evidence of training must be documented;</p> <p>5.2.7 The REB office shall maintain all documentation of SOP training.</p>	<ul style="list-style-type: none"> • All newly revised and approved addendums will be communicated to the Operations Committee, OHSN-REB members and OHSN-REB Office personnel via electronic notification. E.g., email, newsletter, on a quarterly basis (if needed) or sooner if the changes are deemed urgent in nature. • Once addendums are approved, they are posted on the external OHSN-REB website and internal IRIS Guide. • Old versions will be electronically archived indefinitely by the OHSN-REB.

Revision History		
Version Number	Effective Date	Summary of Changes
Version 2	April 6, 2022	Clarification that addenda will be reviewed at minimum every 2 years. In addition, the timeline for on-going review of the main N2 CAREB SOPs will be linked to and rely upon the N2 review cycle.
Version 1	January 12, 2022	Initial Version
This N2-CAREB SOP Addendum has been reviewed and approved by the OHSN-REB Administrative Committee.		