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: # 801 – Clarification on Local Principal Investigator and Research Appointment Requirements

N2-CAREB SOP Guidelines	OHSN-REB Standard Operating Procedure Addendum
5.1 **Researchers Qualifications**	**Who can be listed as the local Principal Investigator (local PI) on the OHSN-REB application?** • All research reviewed by OHSN-REB requires a local TOH/OHRI or UOHI/OHIRC Principal Investigator (local PI). Note, the local PI is responsible for all research activity conducted at their respective institution. • The local PI listed on the application must be the most responsible person conducting and overseeing the research at their respective institution. • The local PI must have completed all research training applicable to the study as required by their respective institution and outlined in the OHRI or OHIRC SOPs. • The local PI must hold an approved research appointment at the applicable institution(s) (OHRI and/or OHIRC). • Investigators at OHRI who hold only an affiliate appointment are not eligible to be listed as a Local PI. For more information about research appointments, please contact the institution's Human Resources Department: o OHRI HR: ohrihr@ohri.ca o OHIRC Research Services: ResearchServices@ottawaheart.ca • **For minimal risk research** (see definition below), the local PI can be a physician or staff member at the respective institution.

- **For above minimal risk research** (see definition below):
    - For regulated interventional trials using drug, natural health products and device studies, the local PI must be a **Qualified Investigator (QI)** (as per Health Canada definition).
    - The Co-Investigator listed on the REB application must be appropriately qualified and trained to assume the local PI responsibilities as necessary. All other Co-Investigators must be listed on the study delegation log.

Who can be listed as the local PI on the OHSN-REB application for trainee/student projects?

- All **trainees/students** applying for review of a project required for their academic credit **must identify their supervisor as the local PI** on the application. This applies to all trainee/student levels:
    - Undergraduate
    - Master's
    - PhD
    - Resident
    - Post-Doctoral
    - Clinical Fellow

Who can be listed as the local PI on the OHSN-REB application for external research projects?

- If an external researcher wants to conduct research at TOH or UOHI they must find a local PI to conduct and oversee the study activity to occur at the respective local site.

Definition for studies Above Minimal Risk:

- "Above minimal risk" research is defined as research in which the probability and magnitude of possible harms implied by participation in the research is **greater than** those encountered by participants in those aspects of their everyday life that relate to the research.
- Examples: clinical trials, interventional research, research involving a vulnerable population, research involving collection/use of various personal identifiers/personal health information

Definition for Minimal Risk Studies:

- "Minimal risk" research is defined as research in which the probability and magnitude of possible harms implied by participation in the research is **no greater** than those encountered by participants in those aspects of their everyday life that relate to the research.
- Examples: Secondary use of information/data or samples, survey/questionnaire studies, focus group or interview studies.

5.2 **Researcher Responsibilities** (as it relates to signatures)**:**	A summary table for the REB application signatures process for local **OHSN-REB and CTO Stream** ethics submissions can be found in Appendix 1 and 2 of the N2 CAREB SOP 801 Addendum. In summary, the QI/PI is required to sign all first time submissions, including the initial application, amendments, reportable events, continuing reviews and study closure. In addition, the REB reserves the right to request the signature of the QI/PI in response to any of the REB's Review Letters. Review Letters will indicate whether QI/PI sign off is required. If the REB does not request the signature of the QI/PI in the Review Letter, a delegate may sign on their behalf. Delegated signatories must be listed on the **study delegation log prior to** assuming this responsibility. A copy of the delegation log may be requested by the Board of Record. Exceptions to the signature process: The Board of Record reserves the right to request the Principal Investigator signature at any time.
	References: • For further details, please refer to relevant OHRI or OHIRC research appointment policy.

Revision History

Version Number	Effective Date	Summary of Changes
Version 5	April 30, 2025	Administrative revisions and clarification for OHRI Affiliated investigator status.
N/A	September 29, 2023	No revision required to addendum N2 CAREB SOP version 801.004
Version 4	December 14, 2022	Updated to reflect changes to OHRI and OHIRC research appointment status requirements.
Version 3	October 2, 2019	Addition of Section 5.2: Researcher Responsibilities; addition of Appendix 1: OHSN-REB Application Signature Requirements; addition of Appendix 2: CTO Stream Application Signature Requirements
Version 2	March 1, 2016	Updated OHRI Appointment statuses
Version 1	April 30, 2015	Initial Version

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