

**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
<p>5.1 Researchers Qualifications</p>	<p>Who can be listed as the Local Principal Investigator (Local PI) on the OHSN-REB application?</p> <ul style="list-style-type: none"> • 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). <p>For more information about research appointments, please contact the institution's Human Resources Department:</p> <ul style="list-style-type: none"> ○ OHRI HR: ohrihr@ohri.ca ○ OHIRC HR: ResearchServices@ottawaheart.ca <ul style="list-style-type: none"> • 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.

<p>5.2 Researcher Responsibilities (as it relates to signatures):</p>	<p>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.</p> <p>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.</p> <p>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.</p> <p><u>Exceptions to the signature process:</u> The Board of Record reserves the right to request the Principal Investigator signature at any time.</p>
	<p>References:</p> <ul style="list-style-type: none"> • For further details, please refer to relevant OHRI or OHIRC research appointment policy.

Revision History		
Version Number	Effective Date	Summary of Changes
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.