

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)

Civic Box 675, 725 Parkdale Avenue, Ottawa, Ontario K1Y 4E9
 613-798-5555 ext. 16719 Fax : 613-761-4311 <http://www.ohri.ca/ohsn-reb>

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. In order to reflect specific OHSN-REB requirements, this addendum complements the N2- CAREB SOP noted below.

N2/CAREB SOP: # 701 – Informed Consent Form Requirements and Documentation

N2 CAREB SOP GUIDELINE	OHSN-REB Standard Operating Procedure Addendum
<p>5.2.4 The REB requires that the translated informed consent materials be submitted for review and approval prior to the use in enrolling non-English/French-speaking participants. The REB may require that the Researcher include a certificate or statement signed by the translator of the REB approved English materials;</p> <p>5.2.5 The REB may follow delegated review procedures to review and approve translated informed consent materials if the English language materials have already been approved (particularly if a signed translation certificate or statement is on file);</p>	<p>Translation Requirements and Official Languages Policy for REB Submissions (TOH & UOHI) The Official Languages Policy for TOH and UOHI remains in effect for all investigators submitting their studies in IRIS and CTO Stream.</p> <p>French Translation Requirement As per institutional policy, French translations of REB-approved English documents are required for all <u>patient-facing materials</u>. This includes, but is not limited to recruitment materials, consent forms, questionnaires, wallet cards and other similar items.</p> <p>REB Submission Language Requirements REB application submissions and all supporting documents (e.g., protocol, consent, participant materials) must be submitted in English. Exceptions may be granted for documents intended to be used exclusively in a non-English format – for example, to validate a French questionnaire.</p> <p>Translation Certificate Requirement Within 30 days of initial REB approval – or approval of an amendment- researchers must upload the translated documents along with a certificate of translation to the <i>Translation</i> tab of the CRRF. This certificate must confirm the quality and accuracy of the translated materials. For OHRI researchers using the OHRI Coordinated French Translation service, both the translated documents and the certificate of translation will be uploaded on your behalf into the <i>Translation</i> tab of the CRRF. An invoice for this service will be issued to the investigator. For details on translation fees, please refer to the IRISGuide.</p> <p>Translation of English documents After REB Approval A guidance document is available on IRISGuide to assist researchers in understanding the translation process at TOH and UOHI for both local and CTO Stream submissions.</p>

	<p>Exemptions from French Translation Requirements for Patient-Facing Documents May Be Considered in the Following Cases:</p> <ul style="list-style-type: none">• The recruitment period is three months or less.• The study does not involve patient participants from TOH or UOHI.• The purpose of the study is to develop or validate a survey tool in one of the official languages.• Student project: An exemption will require proper justification and will be granted at the discretion of the REB Office <p>Translation of French Documents to English Prior to REB Approval For TOH or UOHI researchers participating in a study led by another academic institution where study documents (e.g., protocol, consent forms and other participant-facing materials) are in French, a guidance document is available on IRISGuide outlining the required translation process.</p> <p>Other Translations of Patient Participant-Facing Materials</p> <ul style="list-style-type: none">• OHSN-REB accepts translation of patient-facing materials in languages other than English and French, provided that a certificate of translation from a recognized translation company or certified translator accompanies the REB-approved English document.• A guidance document is available on IRISGuide to support the translation of documents into languages other than English and French.	
Revision History		
Version Number	Effective Date	Summary of Changes
Version 6	April 30, 2025	Revised to remove translation process, clarify translation of documents is a requirement at TOH and UOHI, and the REB supports other translations when applicable.
N/A	September 29, 2023	No revisions required to addendum N2 CAREB SOP version 701.004.
Version 5	December 14, 2022	Revised instruction for when Industry or another lead academic site provides French study documents to indicate that French to English translation must occur prior to REB submission; updated translation process for ethics Amendments due to new electronic Amendment Form.
Version 4	January 12, 2022	Administrative changes (logos, rationale, etc.); revisions to ‘Local OHSN-REB Amendments’ section to indicate REB will send documents to OHRI French Translation Services on study team’s behalf; removal of ‘Validated survey available in English only and study does not have a written consent’ option as translation exemption criteria.
Version 3	February 12, 2020	Added details of new electronic process and verification of PI/Study Team translated documents.
Version 2	March 1, 2016	Administrative changes (letterhead, etc.)
Version 1	June 1, 2015	Initial Version
This N2-CAREB SOP Addendum has been reviewed and approved by the OHSN-REB Administrative Committee.		