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. 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
5.2.4 The REB is required to review all translated informed consent forms and participant facing documents. Translated documents must be reviewed and approved prior to study use for non-English speaking participants. The translated documents must be accompanied by a translation certificate or translation letter equivalent. The guidelines apply to all research studies that involve patient participants at The Ottawa Hospital and/or the University of Ottawa Heart Institute, regardless of who the Board of Record is.	To uphold the principle of respect for the person, as per TCPS2, all patient participant consent forms and patient participant facing materials must be translated. Participants should be offered to read documents in the official language of their choice. Even though a participant can communicate in English, he/she might prefer to read the document in French; therefore, participants must be given the opportunity to read about the study in French or vice-versa. Translation applies to all research studies that involve patient participants at The Ottawa Hospital and/or the University of Ottawa Heart Institute, regardless of who the Board of Record (BOR) is (OHSN-REB, OCREB, CHEO REB or BOR through CTO Stream, etc.). All patient participant facing materials require translation, for example: ○ Informed consent forms, recruitment materials (emails, posters, brochures, etc.), diaries, wallet cards, questionnaires, etc. If Industry or another lead academic site provides French study documents, they must be translated into English prior to submission to REB; **English** documents must be uploaded into the REB application. OHRI French Translation Services may conduct French to English translations for a fee; please email REBAdministration@ohri.ca for more information. In exceptional circumstances, exceptions can be made by the REB Chair (see "Exemptions' below). **Local OHSN-REB Initial IRIS Submissions:** If the translated documents are available at the time of the initial submission, the REB Office can approve in the initial REB approval. Otherwise, documents still requiring translation at the time of REB approval must be uploaded into the 'Translated Documents' tab of the ethics application. A separate approval letter for the translated documents will be issued.

All translated documents must be accompanied by a Certificate of Translation or translation letter equivalent.

Investigators and study teams will be given the option to select who has, or who will be, conducting the translation of each individual document uploaded into the Clinical Research Registration Form (CRRF).

The translation options are as follows:

- **Third Party (i.e., Sponsor, translation company or certified translator) and/or Heart Institute French Translation Services (limited to UOHI Investigators only)**
  *If this option is selected and the translated documents aren't available prior to REB approval, the English documents must be sent to the Translator immediately after REB approval has been issued and the translated documents and corresponding Translation Certificate(s) must be uploaded in the "Translated Documents" tab of the ethics application **prior to day 90** of REB approval.*

- **OHRI French Translation Services**
  If this option is selected, the English documents requiring translation must be uploaded within the applicable sections of the application prior to REB approval. All documents requiring translation will be sent to the Translator by the REB Office.

- **Principal Investigator/Research Study team**
  If this option is selected, the English documents and their corresponding translated version will be sent to OHRI French Translation Services by the REB Office for verification of their quality. If the documents require re-translation, OHRI French Translation Services will conduct the translation and a fee shall be administered for the service.

  - *If the translated document is available at the time of the initial ethics submission, both the English and translated document must be uploaded into the applicable file uploader of the initial ethics application.*

  - *If the translated document is not available at the time of REB submission, it must be uploaded into the "Translated Documents" tab of the ethics application **prior to day 40** of REB approval.*
    - *Note, if the translated document is still pending 40 days after REB approval, the English version will be automatically sent to OHRI French Translation Services for translation and a fee will apply.*

  - *Once OHRI French Translation Service's verification is complete, the Translator will upload a Certificate of Verification, **OR** the translated documents (tracked and clean copy) accompanied by a*

Certificate of Verification Rejection and Certificate of Translation, into the ethics application.

Local OHSN-REB Amendments:

To prevent additional translation costs, it is recommended that Amendment submissions include the English documents only. When the Amendment is approved, it will indicate approval for the English documents.

The same translation options described above for initial applications apply; any documents that need to be translated by OHRI French Translation Services, or that have been translated by the PI/Study Team, will be sent to OHRI French Translation Services by the REB Office on the study team's behalf.

Documents still requiring translation by Third Party, UOHI French Translation Services and/or PI/Study Team at the time of Amendment approval must be uploaded into the *"Translated Documents"* tab of the Amendment Form within 30 days of Amendment approval (15 days for PI/Study Team translations to allow for verification of quality of translation).

A separate approval letter for the translated documents will be issued.

All translated documents must be accompanied by a Certificate of Translation or translation letter equivalent.

Registration Applications (i.e., CTO Stream, OCREB, CHEO-REB)

Investigators who choose to submit their project through CTO Stream or to an external Board of Record must complete the "Translation" tab in the Clinical Research Registration Form (CRRF). All translated documents submitted through CTO Stream or to the external Board of Record (BOR) must be accompanied by a Certificate of Translation or translation letter equivalent.

The translation options are as follows:

- **Third Party (i.e., Sponsor, translation company or certified translator)** and/or **Heart Institute French Translation Services (limited to UOHI Investigators only)**
  - *The CTO Stream or BOR approval letter(s) for French documents and Certificate(s) of Translation must be uploaded into the "Translation" tab of the CRRF* ***prior to day 90*** *of ethics approval.*

- **OHRI French Translation Services**
  - *Upon receipt of CTO Stream or BOR approval, all approved English documents must be uploaded* ***Immediately*** *into the "Translation" tab of the CRRF.*

  - *Upon upload, the documents will be automatically sent to OHRI French Translation Services.*

- *Once completed, the Translator will upload the translated documents accompanied by a Certificate of Translation into the "Translation" tab of the CRRF.*

- *The applicant will then need to submit the translated documents and Certificate of Translation through CTO Stream or BOR.*

- *The REB approval letter(s) for French documents must be uploaded into the "Translation" tab of the CRRF **prior to day 90** of ethics approval.*

- **Principal Investigator/Research Study team**

For submissions through CTO Stream: Investigators are not permitted to translate any provincial participant facing documents themselves; a certified translator must be used. Investigators who choose to conduct the translation themselves can only do so for centre documents.

- *All CTO Stream or BOR approved English documents and corresponding Translated documents must be uploaded into the "Translation" tab of the CRRF **prior to day 40** of ethics approval of the English documents.*
  - *Note, if an English document has been uploaded and the translated document is still pending 40 days after REB approval, the English version will be automatically sent to OHRI French Translation Services for translation and a fee will apply.*

- *Uploaded documents will automatically be sent to OHRI French Translation Services for verification of their quality. If the documents require re-translation, OHRI French Translation Services will conduct the translation and a fee shall be administered for the service.*

- *Once OHRI French Translation Service's verification is complete, the Translator will upload the Certificate of Verification **OR** the translated documents (tracked and cleaned versions) accompanied by a Certificate of Verification Rejection and Certificate of Translation into the CRRF.*

- *The applicant will then need to submit the translated documents accompanied by the Certificate of Verification OR the Certificate of Translation through CTO Stream or BOR.*

- *The REB approval letter(s) for French documents must be uploaded into the "Translation" tab of the CRRF **prior to day 90** of CTO Stream Centre Initial Application approval or BOR approval.*

Amendments for studies submitted through CTO Stream, OCREB and CHEO-REB

	Amendment submissions should include the English documents only. After CTO Stream or BOR Amendment approval, the English documents must be sent to the applicable Translator for translation. The same translation options described above for initial CTO Stream or BOR applications apply; however, any documents that need to be translated by OHRI French Translation Services, or that have been translated by the PI/Study Team, must be sent to OHRI French Translation Services by the Investigator/Study team via email. **Criteria for a Translation Exemption:** Investigators may be granted a translation exemption for the following reasons: ○ Due to short term recruitment (recruitment will be completed within 3 months of the Institutional approval). ○ Participants are Ottawa Hospital/University of Ottawa Heart Institute staff ○ The study does not involve patient participants from The Ottawa Hospital and/or The University of Ottawa Heart Institute ○ Purpose of the study is to create a validated survey in English only ○ Study is recruiting participants from another study ONLY, of which all were English speaking. Exemptions will not be granted because research staff is unilingual or due to funding constraints. If the request for an exemption is denied by the Chair/Vice-Chair/Delegate, the Investigator must provide the translated documents.

Revision History		
Version Number	**Effective Date**	**Summary of Changes**
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.