

***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)***

Applicant User Guide for New Translation Process

Table of Contents

Summary of Changes	2
Instructions when submitting an ethics application to OHSN-REB	3
Instructions when submitting a registration application to OHSN-REB	8

Summary of Changes (see revised **OHRI Addendum to N2/CAREB SOP 701** for complete details)

- All PI/Study Team's translating their own documents (including PI/Study Team's at the Heart Institute) must now have their translations verified by OHRI French Translation Services (i.e. Eric Lepine) for accuracy.
 - If the translation is not accurate, OHRI French Translation Services will re-translate the applicable sections and a fee shall be administered for the service (\$50/hour for time spent making the changes).
- For **initial** ethics and registration applications, all documents being translated or verified by OHRI French Translation Services will be sent through the Clinical Research Registration Form (CRRF) (no longer sent via email), regardless of who the Board of Record (BOR) is.
 - For ethics applications, the applicant will need to select a translation stream (Third Party/Sponsor, UOHI French Translation Services, PI/Study Team, or OHRI French Translation Services) for each document uploaded into the CRRF.
 - For registration applications, the applicant will need to upload the applicable documents for OHRI French Translation Services to translate or verify into Ethics Tab 9 of the CRRF.
 - After initial ethics approval/registration (i.e. Amendments), documents translated by PI/Study Team, or to be translated by OHRI French Translation Services, will need to be sent to Eric Lepine via email.
- Timeline Changes:
 - For ethics applications, all French documents pending at the time of REB approval must be uploaded into Ethics Tab 12 **within 90 days of REB approval**, with the exception of documents translated by PI/Study Team, which must be uploaded **within 40 days of REB approval**. This is to allow OHRI French Translation Services time to verify the PI/Study Team's translation.
 - If the PI/Study Team translated documents are not uploaded within 40 days of REB approval, the English documents will be automatically sent to OHRI French Translation Services for translation and a fee will apply (\$0.25/ word).
 - For registration applications:
 - If OHRI French Translation Services will be conducting the translation, the REB approved English document must be uploaded into Ethics Tab 9 **immediately upon approval**.
 - If the PI/Study Team will be conducting the translation, the REB approved English and corresponding French document must be uploaded into Ethics Tab 9 **within 40 days of REB approval**.
 - As always, the REB approval letter for French documents must be uploaded into Ethics Tab 9 **within 90 days of REB approval**.
- New process for past due French documents:
 - If the translation tab of the CRRF is not fully complete within 90 days of REB approval, a meeting with the REB Chair may be requested.

Instructions when submitting an ethics application to OHSN-REB

Step 1: Upload the English document into applicable file uploader in the CRRF.

Step 2: If available, upload the corresponding French document into the applicable file uploader in the CRRF.

Note, it is recommended that you do not translate any document into French until the REB has reviewed and accepted the English version. If you choose to translate a document prior to REB review of the English version, edits may need to be made to both the English and French translated version, which may result in additional translation costs.

Step 3: Uploaded documents will have a new **Translation** button beside them. For every English document that has been or will be translated, select the **Translation** button of the document. In the pop up, indicate who the translator of the document was/will be, and then click **Submit**:

The screenshot shows a pop-up window titled "French Translation Process" with a close button (x) in the top right corner. The form contains the following elements:

- Document:** English Consent Form.pdf. A blue bracket points to this field with the annotation: "This is the document for which the 'Translation' button was selected."
- Who will be translating the document?** This section contains five radio button options:
 - Third Party (i.e., Sponsor, translation company or certified translator)
 - Heart Institute French Translation Services
 - OHRI French Translation Services (Eric Lepine)
 - Principal Investigator and/or Study Team
 - N/A – Validated Survey/QuestionnaireA blue bracket points to these options with the annotation: "Select the translator of the document here."
- Note:** A yellow highlighted box contains the following text: "If the French documents are available at time of REB submission, they may be uploaded into the applicable section of the ethics application. Otherwise, once approved, all English documents listed below must be translated and uploaded into the 'Translated Document' section of the ethics application **prior to day 90** of REB approval. All translated documents must be accompanied by a Certificate of Translation or translation letter equivalent." A blue bracket points to this note with the annotation: "Instructional text that changes depending on the translation stream selected above."
- Submit** button: A blue button with white text.
- Close** button: A white button with grey text.

Instructions for each translation stream:

Third Party (i.e., Sponsor, translation company or certified translator):

- If the French document is available at time of REB submission, it may be uploaded into the applicable section of the ethics application. *Note, if you choose to translate a document prior to REB review of the English version, edits may need to be made to both the English and French translated version, which may result in additional translation costs.*
Otherwise, once approved, the English document must be translated and uploaded into the “Translated Document” section of the ethics application **prior to day 90** of REB approval. All translated documents must be accompanied by a Certificate of Translation or translation letter equivalent.

Heart Institute French Translation Services

- If the French document is available at time of REB submission, it may be uploaded into the applicable section of the ethics application. *Note, if you choose to translate a document prior to REB review of the English version, edits may need to be made to both the English and French translated version, which may result in additional translation costs.*
Otherwise, once approved, the English document must be translated and uploaded into the “Translated Document” section of the ethics application **prior to day 90** of REB approval. All translated documents must be accompanied by a Certificate of Translation or translation letter equivalent.

OHRI French Translation Services (Eric Lepine)

- Once approved, the English document will be automatically sent to OHRI French Translation Services (Eric Lepine) by the REB Office. The completed translation will be automatically uploaded into the applicable section of the ethics application.

Principal Investigator and/or Study Team

- By selecting this option, the Investigator takes full responsibility for the accuracy and quality of the translation.
- If the French document is available at time of REB submission, it may be uploaded into the applicable section of the ethics application. Otherwise, once approved, the English document must be translated and uploaded into the “Translated Document” section of the ethics application **prior to day 40** of REB approval.
 - If the French document is not uploaded within 40 days of REB approval, the English version will be automatically sent to OHRI French Translation Services for translation and a fee will apply.
- The translated document will be automatically sent to OHRI French Translation Services to verify the accuracy and quality.
Note, should concerns arise, the document will be retranslated by OHRI French Translation Services and the Investigator will be charged a translation fee.

N/A- Validated Survey/Questionnaire

If the French validated Survey/Questionnaire is available at time of REB submission, it may be uploaded into the applicable section of the ethics application. Otherwise, once ethics approval has been granted, the validated French version must be uploaded into the “Translated Document” section of the ethics application **prior to day 90** of REB approval.

STEP 4: After REB Approval

After REB approval has been granted, all documents that were pending French translation at the time of ethics approval will be listed at the top of Ethics Tab 12: Translated Documents, in the “Pending French Documents” section. The documents will be categorized based on the Translation Stream that was selected for the English documents in the ethics application (Third Party, Heart Institute French Translation Services, PI/Study Team, and OHRI French Translation Services).

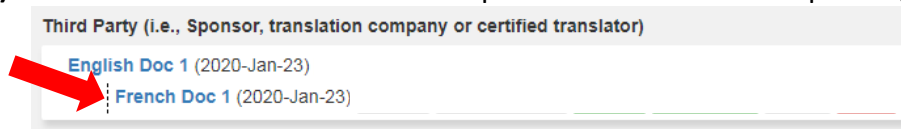
A) Below the list of documents is a File Uploader. At the top of the File Uploader there is a drop-down list of all of the English documents that are listed above it. Select the English document that corresponds with the French version you wish to upload.

B) Click ‘Choose File’ to select the corresponding/matching French version.

C) Click ‘Upload’

The screenshot shows a 'File Uploader' form with an orange header. Below the header, there is a dropdown menu labeled 'Select related file: (if applicable)' with 'English Doc 1' selected. A red box labeled 'A)' highlights this dropdown. Below the dropdown, there is a text prompt: 'Please select a file to upload (each file can be no larger than 10 MB) Permitted file types include extensions .doc, .docx, .xls, .xlsx, .pdf, .jpg, .jpeg, .bmp, .png, .gif, .txt, .ppt, .pptx.' Below this, there is a red box labeled 'B)' containing a 'Choose File' button and the text 'No file chosen'. Below the 'Choose File' button, there is a text prompt: 'Please enter a short description for this file:' followed by a text input field. A red box labeled 'C)' highlights an orange 'Upload' button at the bottom left of the form.

D) The French document will now be uploaded below it's corresponding English version:



For documents translated by **'Third Party', 'Heart Institute'** and **'N/A: Validated Survey/Questionnaire'**:

- Upon upload, the document will be submitted to the REB for review. It is your responsibility to ensure the correct document is uploaded.

For documents translated by **PI/Study Team**:

- All documents pending French translation by the PI/Study Team must be translated and uploaded **within 40 days of REB approval**.
- After uploading the French version, click the **Submit** button located beside the English document. Once this is selected, the English and corresponding French version will be sent to OHRI French Translation Services for verification.
 - If the translation is **acceptable**, you will receive an automated email once the verification is complete and the Certification of Verification will be uploaded by OHRI French Translation Services.
 - If the document **requires re-translation**, you will receive an automated email once the re-translation is complete and the new translated document will be uploaded by OHRI French Translation Services. The translated document will be accompanied by a tracked version showing all of the changes that were made, a Certificate of Verification Rejection explaining why the translation was not accepted, as well as a Certificate of Translation. *Note, a fee shall be administered for the re-translation.*
 - Once all applicable documents are uploaded by OHRI French Translation Services, they will be available to the REB for review (no action required on your end).

For documents translated by **OHRI French Translation Services**:

- You will receive an automated email once the translated document has been uploaded by OHRI French Translation Services. The translated document will be accompanied by a Certification of Translation.
- Once all applicable documents are uploaded by OHRI French Translation Services, they will be available to the REB for review (no action required on your end).

E) If the Principal Investigator/Study Team **and/or** OHRI French Translation Services conducted any translations prior to REB approval, or if either will be conducting any translations after REB approval, provide a Cost Centre in **Section 142** in the event that an invoice needs to be created:

142. Cost Centre for French Translation Invoice

If the Principal Investigator/Study Team and/or OHRI French Translation Services conducted (or will be conducting) any translations, provide the Cost Centre for the invoice: (E12.142.2052)

F) In **Section 52**, upload all applicable Translation Certificates:

Note: A Certificate of Verification and Certificate of Translation will automatically be uploaded for all translations conducted by OHRI French Translation Services.

Step 5: Once available, the REB's approval letter for the Translated Documents will be uploaded into 'Section 136: REB Approval Letter for Translated documents', and you will receive an automated email.

**Instructions when submitting a registration application to OHSN-REB
(ethics application is submitted through CTO Stream, or to an external Board of Record (BOR))**

All questions relating to French documents are now present in **Ethics Tab 9: Translation**.

Instructions for translations conducted by Third Party or UOHI French Translation Services:

- Step 1:** Complete **Section 138 (Section 141 for CHEO-E applications): Translated Documents** and upload the REB approval letter(s) for the French documents into the applicable questions.
- Step 2:** In **Section 130: Certification of Translation and Additional Translation Documents**, upload all Third Party and UOHI Translation Certificates.
- Step 3:** Once all questions have been addressed, submit the tab to the OHSN-REB Office for review by clicking the **Submit** button at the bottom of the tab. *The Translation tab must be submitted to the OHSN-REB for review within 90 days of REB approval.*
- Step 4:** Once no further changes are required, OHSN-REB will mark the Translation Tab 'Complete' and you will receive an automated email.

Instructions for translations conducted by the PI/Study Team or by OHRI French Translation Services:

- Step 1:** Complete **Section 138 (Section 141 for CHEO-E applications): Translated Documents**.
- Step 2:** If the **PI/Study Team** or **OHRI French Translation Services** will be conducting any translations, upload the REB approved English documents into the File Uploader above Section 138 (Section 141 for CHEO-E applications):
 - A) Select the Translator
 - B) Choose the File
 - C) Click 'Upload'

File Uploader

Select related file: (if applicable)

A) Translated by:

- OHRI French Translation Services (Eric Lepine)
- Principal Investigator and/or Study Team

Please select a file to upload (each file can be **no larger than 10 MB**) Permitted file types include extensions .doc, .docx, .xls, .xlsx, .pdf, .jpg, .jpeg, .bmp, .png, .gif, .txt, .ppt, .ppbx.
Upload translated documents, using the same naming convention that was used for the English version; be sure to select the file the upload is in relation to:

B) No file chosen

Please enter a short description for this file:

C)

IMPORTANT: If OHRI French Translation Services is translating, the uploaded document will automatically be sent for translation. It is your responsibility to ensure the correct document is uploaded.

Step 3: If the **PI/Study Team** has conducted any translations, upload the applicable French documents into the File Uploader:
 (if applicable) *All documents pending French translation by the PI/Study Team must be translated and uploaded within 40 days of REB approval.*

- A)** Select the English file to which the French version you are about to upload corresponds to
- B)** Select the Translator
- C)** Click 'Choose File' to select the corresponding/matching French version
- D)** Click 'Upload'

File Uploader

A) Select related file: (if applicable)

B) Translated by:

- OHRI French Translation Services (Eric Lepine)
- Principal Investigator and/or Study Team

Please select a file to upload (each file can be **no larger than 10 MB**) Permitted file types include extensions .doc, .docx, .xls, .xlsx, .pdf, .jpg, .jpeg, .bmp, .png, .gif, .txt, .ppt, .ppbx.
Upload translated documents, using the same naming convention that was used for the English version; be sure to select the file the upload is in relation to:

C) No file chosen

Please enter a short description for this file:

D)

Upon upload, both the English and PI/Study Team translated French version will automatically be sent to OHRI French Translation Services for verification. It is your responsibility to ensure the accurate documents are uploaded.

Step 4: If the **PI/Study Team** conducted the translation:

- If the translation is **acceptable**, you will receive an automated email once the verification is complete and the Certification of Verification has been uploaded.
- If the document **requires re-translation**, you will receive an automated email once the re-translation is complete and the new translated document has been uploaded. The translated document will be accompanied by a tracked version showing all of the changes that were made, a Certificate of Verification Rejection explaining why the translation was not accepted, as well as a Certificate of Translation. *Note, a fee shall be administered for the re-translation.*

If **OHRI French Translation Services** conducted the translation:

- You will receive an automated email once the translated document has been uploaded. The translated document will be accompanied by a Certificate of Translation.

Step 5: Once the **PI/Study Team** and/or **OHRI French Translation Services** verifications/translations are complete, submit the French documents and Certificate of Verification/Translation through CTO Stream or to the external Board of Record for approval.

Step 6: In **Section 138 (Section 141 for CHEO-E applications): Translated Documents**, upload the REB approval letter(s) for the French documents into the applicable questions.

Step 7: In **Section 130: Certification of Translation and Additional Translation Documents**, upload all Third Party and UOHI Translation Certificates. *Note, all Certificates of Translation and Verification from OHRI French Translation Services will auto upload to here.*

Step 8: Once all questions have been addressed, submit the tab to the OHSN-REB Office for review by clicking the **Submit** button at the bottom of the tab. *The Translation tab must be submitted to the OHSN-REB for review within 90 days of REB approval.*

Step 9: Once no further changes are required, OHSN-REB will mark the Translation Tab 'Complete' and you will receive an automated email.