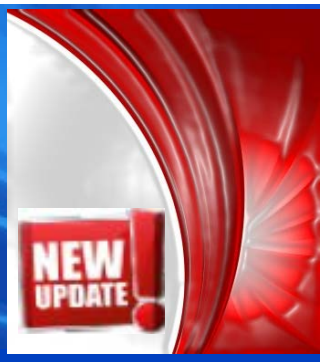
OHSN-REB TOP 10 UPDATES

SEPTEMBER 13TH, 2021



Please share the following important REB Top 10 list with your research study teams.

1

New Timelines and Process for Reviewing REB Submissions

On September 13th the REB will implement and pilot test a new process for reviewing initial applications and amendments. Review the links below for instructions and process maps. The new review process will require a collaborative team effort from the investigator, study team, REB Office and Contracts Office. The information below is also posted on the OHSN-REB website under the "Instructions and Review Process" tab.

- Instructions and Process Map for Full Board Application Review
- Instructions and Process Map for Delegated Prospective Application Review
- Instructions and Process Map for Secondary Use Application Review
- Instructions and Process Map for Amendment Review

To help facilitate a timely REB review and improve submission to approval turnaround times, the REB Office is now promoting bi-weekly remote MS Team huddle meetings**.** Please see the schedule below for dates and times and who can request a huddle. Alternative arrangements can be made should these dates / times not work for the investigator or study team!

- TOH Schedule for Remote MS Team Huddles
- Heart Institute Schedule for Remote MS Team Huddles

Who can request a huddle meeting?

- **Investigators and study teams**
  For example:
  - ✓ Prior to REB submission (strongly recommended for complex studies)
  - ✓ After receipt of preliminary concerns or review letter
- **REB Office**
  For example:
  - ✓ Prior to review of the application should the application be incomplete
  - ✓ After review of the application should clarification be required
- **Contracts Office, Facilitators, and/or Privacy Office**
  For example:
  - ✓ To confirm a study is considered a Phase IV (regulated, but no CTA required)
  - ✓ To determine if a contract/agreement is required

- ✓ To review participant privacy and data security protections related to an unknown device or platform proposed for use in a study

Note, collaborative huddles involving all applicable parties (study team, REB, Contracts, Facilitators, Privacy Office and/or IT) are encouraged.

How can a huddle meeting be arranged?

- ➢ Huddle requests should be sent to REBAdministration@ohri.ca
  - ✓ Requests should include the following:
    - CRRF ID and / or protocol number, study name and acronym
    - Names and emails of personnel to be invited to the huddle
    - Summary for the huddle request
    - List of dates and times available (see REB schedule for remote MS Team huddles)
    - Anticipated duration of huddle (e.g., 30, 60 or 90 minutes)

How will the new huddle meetings benefit you?

- ✓ Provides better communication between the REB Office, Investigator, Research Teams, and Research Administration.
- ✓ Demonstrates commitment by the REB Office, Investigator and study team from time of submission to study approval.
- ✓ Improves facilitation and enables learning and growth.
- ✓ Reduces turnaround times to approval and reduces back and forth email dialog between investigators, applicants and REB office promoting better time management.

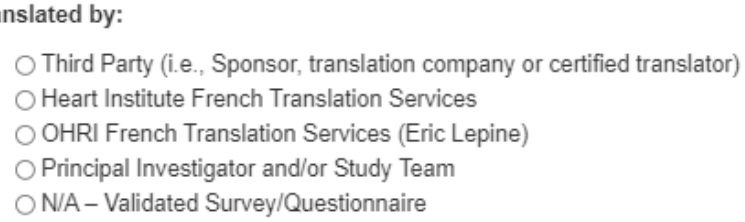
2 **Translation Process**

- Applicant User Guide for Translation Process
- CRRF Ethics Applications - Translation Process Map
- CRRF Registration Applications - Translation Process Map

Initial CRRF Ethics Applications:

- 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 within 90 days of REB approval (40 days for PI/Study Team translations). A separate approval letter for the translated documents will be issued.

- If a document still requires translation at the time of REB approval, select the Translation button to inform the REB who the translator will be:



If *'OHRI French Translation Services'* or *'Principal Investigator/Study Team'* are selected, the applicable documents will be sent to OHRI French Translation Services through the CRRF by the REB to verify the quality of the translation.

Initial CRRF <u>Registration</u> Applications:

- The REB approval letter for French documents must be uploaded in the 'Translation' tab of the CRRF within 90 days of REB approval.

- If OHRI French Translation Services **or** PI/Study Team are translating, the applicable documents must be sent to OHRI French Translation Services through the 'Translation' tab of the CRRF.

Amendment Forms:

- If the translated documents are available at the time of the Amendment submission, the REB Office can approve in the Amendment approval. Otherwise, documents still requiring translation by Third Party, UOHI French Translation Services and/or PI/Study Team at the time of Amendment approval must be sent to REB within 30 days of Amendment approval (15 days for PI/Study Team translations to allow for verification of quality of translation).

- **Important**: If PI/Study Team and/or OHRI French Translation Services (Eric Lepine) will be translating, the REB will send the applicable documents to Eric Lepine directly on the study team's behalf. See the OHSN-REB Top 10 Update of July 28, 2021 for details.

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

3 <u>OHSN-REB Consent Templates have been Updated on the OHSN-REB Website</u>

Please visit the OHSN-REB website "Guidance and REB Templates" tab as most of the templates have been updated. Use of the templates enables the REB to review effectively, efficiently and rapidly. If the consent templates are not used, the application will be returned with a request to resubmit using the REB consent form templates.

The following templates are available and must be used with your submission to the REB:

- ✓ Clinical Trial Consent
- ✓ Minimal Risk Consent
- ✓ Oncology Clinical Trial Consent
- ✓ Optional Consent (i.e., genetics, biological samples)
- ✓ Pregnant Partner Consent
- ✓ Update Consent (for re-consent purposes only)
- ✓ Verbal Consent (for minimal risk studies)
- ✓ Implied Consent (for minimal risk studies only)

4 Reminders for Studies Submitted through CTO Stream

1. Research Administration relies on an electronic web-based application called the Clinical Research Registration Form (CRRF) for tracking all research being conducted on site **or** by our researchers. All clinical research activity must be registered in the CRRF, including studies submitted through CTO Stream, whether applying as a provincial lead or participating site.

2. There are two types of CTO applications (i.e., Clinical trials application and observational application). The Provincial Applicant **must** use the applicable CTO Stream ICF template when creating a Provincial ICF for a study:

   - ✓ Important Notice – Mandatory Use of CTO ICF Template as of May 1, 2019
   - ✓ Clinical Trial Consent Template
   - ✓ Observational Consent Template

   When a new provincial application is submitted, CTO will review the main study ICF to ensure it follows the structure and format of the applicable CTO ICF template. If the ICF does not match the CTO template, the application will be screened as incomplete by CTO and returned to the applicant.

   Centre Applicants must use their study's provincially approved ICF template to create their centre specific ICF.

3. Translation of documents still applies when submitting through CTO Stream.

   In the 'Translation' tab of the CRRF, study teams must indicate who will be conducting the translation of all patient facing documents that will be used at TOH and/or UOHI as explained in #2 above.

For more CTO Stream Information, please visit the Clinical Trials Ontario website or OHSN-REB website "Application and Submission Process" tab.

5 Virtual Remote Recruitment and Consent Section has been Updated on OHSN-REB Website

Please visit the "Guidance and REB Templates" tab of the OHSN-REB website for updated information on Virtual/Remote Recruitment and Consenting processes for studies requiring written consent.

6 Reminder for Email Correspondence with the OHSN- REB

General Email Correspondence:

In general email correspondence with the REB, please ensure to provide the following information so that we may better assist you and provide a prompt response:

1. **Subject Line**:
   - ✓ CRRF Number, Protocol Number, Acronym, purpose of email (e.g., inquiry of…)
2. **Body of Email**:
   - ✓ Regarding: CRRF number, protocol number, study acronym and title, PI and Co-I, study staff, if applicable

- ✓ Purpose of correspondence (use bullets to summarize)

Post Approval Email Correspondence:

On a daily basis, the REB Office receives a high volume of post approval submissions (i.e., Amendments, Reportable Events, Continuing Reviews, Study Closure). To ensure your submission is appropriately triaged and reviewed in a timely fashion, please follow the attached "Email Requirements when Submitting Post Approval Forms" instructions.

7 **Reminder for Reportable Event Submissions**

To submit a Reportable Event to the REB, **BOTH** of the following forms must be enclosed:

- ✓ Main Reportable Event Form
- ✓ Applicable Event Section Form

Each event must be submitted individually (i.e.: one applicable event form per each selected item on the Main Reportable Event Form). For example, if there are two Local (Internal) Serious Adverse Events/Unanticipated Problems to report, a Main Reportable Event Form and Local SAE Section Form must be submitted for **each** event.

8 **Reminder for Amendment Submissions**

The REB's Amendment Form has been updated and the updated version is posted on the OHSN-REB website.

At the time of every submission, download the applicable form directly from the OHSN-REB website to ensure you are completing the most recent version.

9 **Reminder for Continuing Review Submissions**

The Continuing Review Form must be received **no** later than 40 days and no earlier than 50 days prior to your current approval **expiration date.** The REB requires adequate time to review your submission prior to expiration.

- If your Continuing Review requires review by the Full Board, please submit by the appropriate full board meeting deadline.

If you are working on multiple projects, it is important to document REB expiry dates in your Outlook calendar and to set up an Outlook reminder for the submission window of ≥40 days and ≤50 days prior to the study expiry date.

Consequences of study expiration:
As per TCPS2, REBs are not able to grant extensions, therefore planning for your continuing renewal submission is essential.

- ➢ A warning or suspension letter notice will be issued to the Researcher and your Department's Research Manager will be notified.
- ➢ Must suspend all research activities including recruitment, data analysis, and study visits.

- If participants were recruited during expired status - the Chair/Vice-Chair of the REB may rule that the participants must be withdrawn, and data may not be used.
- Project cost centre may be frozen, and expenses/transfers/payments will not be processed until continuing review has been approved, this may impact payroll.
- You may encounter issues trying to publish.
- The REB may choose to close expired studies.

All lapses in approval will be documented in the REB's study file as well as in the REB letter renewing the study (visible to monitors, auditors, and inspectors).

10 **Expired Studies**

In local IRIS:
All OHSN-REB approval letters indicate the study expiry date. A study is usually approved for 365 days unless otherwise indicated in the approval letter. The REB office issues one warning via email that a study closure or continuing review form is required ASAP. If either is not received within 10 days of the notice, the study will be closed by the REB.

In CTO Stream:
The expiry date for CTO studies is in accordance with the provincial application. When the provincial application expires, all the centre initial applications expire at the same time. CTO studies are usually approved for 365 days unless otherwise indicated.

Upon expiry, automated emails are sent from CTO Stream to inform the Principal Investigator, study staff (who are listed on the application), and Institutional Representatives (OHRI – Amy Geertsma and Nancy Camack, UOHI – Sharon Finlay and Megan Reilly).

If a study closure or continuing review form is not submitted, the Board of Record can close the study within 10 days of the expiry date.

Please see the following links for further information on CTO Study Expiry Dates:

- Provincial Status and Expiry Date
- Centre Status & Expiry Date

If you would like to request a virtual MS Team meeting with the REB Chair or REB Manager, please contact REBAdministration@ohri.ca