OHSN-REB Top 10 Updates

March 14, 2023

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

1

Clinical Trials Ontario (CTO) Stream – Supports REB Harmonized Review

Are you aware of the Clinical Trials Ontario – CTO Stream REB Application which supports REB harmonized review for multi-centre research?

CTO supports applications for both Industry Sponsored and Investigator-Initiated trials by providing a process for harmonized review in Ontario. Currently there are over 150 sites who have entered into a participation agreement with CTO. If your research involves 2 or more sites in Ontario, check the CTO participating site list found on the CTO website. If the site is listed, a streamlined research ethics process can be conducted by submitting a CTO Stream REB Application!

What does CTO streamlined research ethics review mean?

- ✓ One REB is chosen as the 'Board of Record' to conduct the review on behalf of the lead site and all participating centres/sites located in Ontario.
- ✓ If you are looking to conduct a study at multiple sites in Ottawa, know that The Ottawa Hospital, University of Ottawa Heart Institute, Children's Hospital of Eastern Ontario (CHEO), Hôpital Monfort, Bruyère Hospital and the Royal Ottawa Hospital are all CTO participating hospital institutions and therefore CTO Stream may be utilized!
- ✓ In addition, OHSN-REB, CHEO REB and Monfort REB are all 'CTO Qualified REBs' and may be assigned as the Board of Record for any project submitted through CTO Stream to review on behalf of all participating sites.
- ✓ For more information on CTO submissions and how the process works at TOH / UOHI, please click here.

2

Clinical Trials Ontario (CTO) Stream – Supports Observational / Delegated Studies

Are you aware that you can submit a CTO Stream application for non-clinical trials?

- ✓ Investigators and study teams can submit provincial and centre applications in CTO Stream for multi-centre non-interventional/observational studies!

3 Revised OHSN-REB Addendums to N2 CAREB SOPs

Please review the changes to the following two revised OHSN-REB Addendums:

- ✓ OHSN-REB Addendum to N2 CAREB SOP 701 (RE: Translation Requirements)
  - Revised to include the following:
    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.

- ✓ OHSN-REB Addendum to N2 CAREB SOP 801 (RE: Who can be listed as Principal Investigator)
  - Re-written entirely for clarity on who can be a principal investigator for OHRI and OHIRC studies and who to contact regarding OHRI and OHIRC research appointment requirements.

4 Use of Third-Party Technologies at TOH and/or UOHI

Prior to creating a Clinical Research Registration Form (CRRF), review the study Protocol in detail to determine if the TOH/UOHI Privacy/IT "Request for Use of Third-Party Technologies at TOH and/or UOHI" Form will need to be completed.

If required:

- ✓ The form must be completed by the study team with support from the sponsor prior to sending to the respective Privacy and IT offices for review. Note, it can take a minimum of 4-6 weeks for a full Privacy and IT office review/approval.

- ✓ After Privacy and IT approval of the Third-Party Technology, the signed form and any email correspondence from Privacy and IT Offices must be uploaded into the 'Notifications' tab of the CRRF prior to submission of the tab.

- ❖ The REB and Contracts Offices rely on Privacy and IT's review to ensure the REB application, consent form and contract align with institutional policies. Therefore, the REB and Contracts Offices cannot conduct their review until evidence of Privacy/IT approval has been uploaded.

  The "Request for Use of Third Party Technologies at TOH and/or UOHI" Form can be found on the REB's page of IRISGuide here:

5 Reminder: When revising documents, tracked and clean copies are required!

When revising documents, be sure to upload tracked (showing the changes) **and** clean versions. The REB requires a tracked copy in order to review the changes that have been made as well as a final clean copy to approve.

6 Updates to Old Consent Forms

At the time of every Continuing Review, if recruitment is open, check your study's consent form to ensure it aligns with the OHSN-REB's current consent form template. This is particularly important if your study is funded or supported by a US federal funding agency and/or involves genetic testing and/or future optional research as new language requirements (e.g.: Summary of ICF page) were added February 2022.

If changes are required, submit an Amendment Form to the REB, independently of the Continuing Review Form.

7 Do NOT Delete Uploaded Documents in CRRF

Unless specifically instructed to by the REB office, do **not** delete any documents that are uploaded in the Clinical Research Registration Form (CRRF). For example, if you are asked to revise a consent form, do not delete the consent form that was initially uploaded and reviewed by the REB; simply upload additional documents as requested. All uploads must remain for auditing and monitoring purposes.

8 Email Correspondence with the OHSN- REB

In all email correspondence with the REB, provide the following study information so we may better assist you and provide a prompt response:

- ✓ CRRF ID/OHSN-REB Protocol number/CTO ID
  - ❖ If it is post approval form, provide Post Form ID & type of post form (Amendment, Continuing Review, Reportable Event, Study Closure)
- ✓ Full Study Title and Principal Investigator name

9 Reportable Event Submissions

The OHSN-REB SOPs can be found on IRISGuide under the Policies and SOPs section to determine if an event is reportable to the REB. Please review the OHSN-REB N2 CAREB SOP 404 and addendum an appendix for submission details and deadlines.

The following is a list of reportable event types reportable to the REB:

- ✓ Local (internal) Serious Adverse Event / Unanticipated Problem
- ✓ Non-Local (external) Serious Adverse Event / Unanticipated Problem
- ✓ Periodic Safety Update Report (SUADR, CIOMS, etc.)
- ✓ Safety Notice / Update Report (i.e., action or safety letter issued by regulatory authority or sponsor)
- ✓ Audit / Inspection Report
- ✓ Protocol Deviation
- ✓ Privacy Breach
- ✓ Study Participation Complaint
- ✓ Pregnancy Partner Event
- ✓ Other Reportable Event

For more information on these types of reportable events, please review the annotated Reportable Event form found on IRISGuide under the templates, Forms and Guidelines section.

10	**REMINDER - Institutional Approval is required prior to study start** An **Institutional approval** letter from OHRI or OHIRC is required prior to study start. Institutional approval is granted once the Ethics, Contracts and Departmental Notifications tabs of the Clinical Research Registration Form (CRRF) are approved/marked complete by the reviewing office. **Institutional approval** is the green light to start your study at TOH/OHRI or UOHI/OHIRC. 

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