Distribution: OHRI- Clinical Research Scientists, Investigators, Staff, Trainees and Administrative Staff
REB Applicants

Sent on Behalf of Amy Geertsma, REB Manager

Hi All,

The OHSN-REB will be sending out new communication and updates via the "OHSN-REB Top 10" list monthly. If you would like to meet with the Chair or REB Manager, please send meeting requests to REBAdministration@toh.ca so that arrangements can be made to meet via MS Teams. The Chair and REB Manager are happy to meet with you about any concerns you may have regarding new complex studies (preferably prior initial submission), amendments, discrepancies written in review letters, delays with review, and any other concerns.

Thank you.

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

1

Survey/Data Collection Platforms

REDCap, LimeSurvey and Microsoft Forms are available at TOH for electronic surveying and data collection. The use of outside tools such as Survey Monkey and others are strongly discouraged since collected data will be saved outside of TOH. Click here for further details.

2 Timing of NOL Submission for Drug Trials

- For **Industry sponsored** studies, the NOL must be provided at the time of initial submission.

- For studies **Investigator- Initiated by Other Academic Centre**, the NOL must be provided at the time of initial submission.
- For studies **Investigator- Initiated by TOH/OHRI or UOHI/OHIRC**, the NOL must be provided at the time of initial submission **or** at minimum, the REB must be provided proof that the CTA has already been submitted and received the 30-day response from Health Canada (for example, upload the email trail with Health Canada).

- For TOH and UOHI investigators submitting a Provincial Initial Application (PIA) in CTO Stream, the NOL must be provided at the time of initial submission.

- The REB may consider exceptions to the standards above. A request must be emailed to REBAdministration@toh.ca with justification for seeking an exception prior to submission of the initial REB application without the NOL.

3 Protocols Require Version Dates

For all TOH/OHRI or UOHI/OHIRC Investigator initiated studies (this includes Medical Student/Resident/Fellow Research), the Protocol should **always** be uploaded with a version date in the footer of the document. A version number is not necessary.

4	**Documents in the Clinical Research Registration Form (CRRF)** Once an application has been submitted in the CRRF for review, no document should ever be deleted from the application unless you've been directly instructed to do so.
5	**Translation of Validated English Questionnaires** If an English questionnaire tool is validated and **not** available in French, the document **cannot** be translated into French unless permission from the author has been obtained. If this is an issue for the study, consider locating a similar tool that **is** available in both languages. Ensure you have investigated and confirmed that a validated French version does not exist. Just because it wasn't provided by the sponsor or lead academic site, it doesn't necessarily mean a validated French version doesn't exist.
6	**Selecting the Translation Option for each uploaded Participant Document is Required** The 'Translation' button must be selected every time a participant facing document is uploaded. This is often the last piece of information the Research Ethics Coordinator needs to be able to process an approval; approval is delayed when not selected.
7	**Uploading Translation Certificates** Before submitting the Certificate of Translation, ensure that the referenced version dates of the English and French documents match the actual version dates English and French documents in question.

8 CHEO and OHSN REB Harmonization Agreement

As of December 18, 2019, studies falling under the jurisdiction of both CHEO and OHSN REB (i.e., due to Investigator affiliations and/or study activity at both sites) no longer require two separate ethics applications.

Instead, CHEO REB and OHSN REB will work collaboratively to review and approve the research studies via one ethics application. There will be a single Research Ethics Board of record assigned.

Note, if in addition to CHEO and/or TOH/UOHI, the research will be conducted at multiple site in Ontario who are participating sites in Clinical Trial Ontario (CTO), the research study should be submitted through CTO Stream instead of through the Harmonization Agreement.

What is the process?

1. Study teams must complete a REDCap Survey: TOH & CHEO REB Harmonization
2. After CHEO and OHSN REB review the REDCap Survey, study teams will receive further instruction.

9 REB Continues to Work Remotely during COVID-19

All post approval submissions (i.e.: Amendment Forms, Continuing Review Forms, Reportable Event Forms, Study Closure Forms) must be submitted to the REB via email to REBadministration@toh.ca.

- Please include the REB Protocol Number as well as the submission type in the email subject line. For example: "Protocol # 20200123-01H: Amendment Form dated March 9, 2021".

- If submitting a Continuing Review Form, also include the study's expiration date **and** type of review requested (Full Board or Delegated) in the subject line to help the REB office ensure ethical approval does not lapse.

For example:

- Protocol # 20200123-01H: Continuing Review Form – February 20, 2021 Full Board Meeting - Expires March 17, 2021
- Protocol # 20200123-01H: Continuing Review Form - Delegated Review - Expires March 17, 2021

- If PI signature cannot be obtained on the REB post approval form due to remote work, the submission should be submitted to REB directly by the PI, or by a research team member with the PI cc'd.

10

New Process for Amendments and Documents to be Reviewed

For amendments that require revision to any study document(s), the REB requires the tracked-changed and clean copy document(s) for review.

What is new?

- The REB will make changes to the tracked-changed document (not the cleaned copy). The tracked-changed document should display **all** REB, applicant and sponsor (if applicable) comments, edits and changes in its entirety from the time of initial amendment submission to amendment approval.

- The REB will highlight the initial comments in yellow, 2nd round of comments in turquoise, and 3rd round of comments (if applicable) in fuchsia.

- All REB comments within the document must be addressed prior to returning to the REB. If any changes in addition to those requested by the REB are made, they must be color coded as above and a comment inserted with justification to alert the REB that the changes are new, still requiring review.

- A new cleaned copy must be provided with each subsequent response to the REB so that approval can be readily issued.

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

Jessica Djayaputra
Research Ethics Administrative Assistant
Ottawa Health Science Network Research Ethics Board (OHSN-REB)
Ottawa Hospital Research Institute

The Ottawa Hospital Research Institute | L'Hôpital d'Ottawa Institut de recherche

Inspired by research. **Driven** by compassion.
Inspiré par recherche. **Guidé** par la compassion.

725 Parkdale Avenue, Civic Box 675, LOEB Building, Ottawa, ON, K1Y 4E9
T: 613-798-5555, 16719 | F: 613-761-4311 | jdjayaputra@ohri.ca

www.ohri.ca/ohsn-reb