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

Sent on Behalf of Amy Geertsma, REB Manager

OHSN-REB TOP 10

MAY 17, 2021

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

The REB Office will be presenting an education session on Thursday May 20th, 2021 - 10:00 to 11:30 a.m.
on the "Virtual Consenting Process for Studies Requiring Written Consent"

This session will provide details on the virtual consenting process and provide options for collecting remote consent from participants when research staff and participants cannot meet in-person.
The REB will provide clarity on the REB submission requirements which align with institutional privacy and IT policies.

Please click here to join the meeting.

1 **Use of Virtual Platforms in TOH/OHRI or UOHI/OHIRC Investigator Initiated Studies**

The REB **will approve** the following virtual platforms for use at TOH and UOHI:

- ✓ Ontario Telemedicine Network (OTN) (participants must be patients in Ontario)
- ✓ Epic Telehealth (currently powered by Zoom) (video requires a "patient encounter/appointment" in Epic)
- ✓ Zoom for Healthcare outside of EPIC (for UOHI only)

- ✓ Microsoft Teams

TOH and UOHI IT Services strongly encourage the use of the platforms listed above. If you require a different licensed platform for your study, please follow the instructions below to contact TOH Audiovisual Services or UOHI IT for support:

- ✓ TOH/OHRI study teams:
  - Requests to purchase a license for a new virtual platform must be submitted to TOH IT Audiovisual Team by completing the Request for Use of an Alternative Virtual Platform at TOH form. Please submit directly to Alain Audette, TOH Senior Technology Analyst & Audiovisual Team Lead at aaudette@toh.ca.
  - TOH IT must obtain the license as it is their responsibility to ensure the security and protections are in place (PHIPA compliant) prior to use to protect staff, patients and other participants.
- ✓ UOHI/OHIRC study teams:
  - Requests to use other virtual platforms must be submitted directly to the UOHI IT Help Desk.
- ✓ **The REB will require evidence of approval from TOH Audiovisual Services or UOHI IT prior to issuing REB approval for use of any alternative platform.**
- ✓ **The REB will not approve "free" non-licensed platforms as they are not secure/encrypted**.

2 Use of Survey Tools in TOH/OHRI or UOHI/OHIRC Investigator-Initiated Studies

The REB **will approve** use of the following survey tools, **acceptable to TOH and UOHI IT security**:

- Office 365 Microsoft Forms
- LimeSurvey
- TOH REDCap (cannot be accessed outside of TOH network)
- UOHI REDCap under the direction of CRMC

Visit the TOH Analytics Department Survey Tools SharePoint Site, or for questions contact tohsurveys@toh.ca.

For Office 365 Microsoft Forms and other Microsoft Office 365 support:

- ✓ Microsoft Forms Virtual Lab
- ✓ Microsoft Forms Help and Learning
- ✓ Post a question in the M365 Business Analysts' MS Team User Support 'Questions' Channel or open an incident in Service Now (servicenow@toh.ca).

3 Use of Third-Party Services in TOH/OHRI or UOHI/OHIRC Investigator-Initiated Studies

The REB **will not approve** the use of third-party services in TOH/OHRI or UOHI/OHIRC Investigator- Initiated studies without evidence of approval from the institution's IT Services (see instructions below). Examples of third-party services include but are not limited to:

- ✓ 3rd party commercial service provider (i.e., Amazon Suite, Microsoft Azure)
- ✓ Company provided Cloud server
- ✓ Device based Apps (downloaded or installed onto a smartphone or other device)

For TOH/OHRI, the REB will require evidence of approval from the TOH Business Analysts Team; please complete the Request Form for Use of Third-Party Commercial Service at TOH/OHRI (coming soon) and submit an incident to ServiceNow@toh.ca.

For UOHI/OHIRC, approval must be obtained from UOHI IT and/or the Privacy Officer, as applicable (For Full Board REB studies, this approval may be imbedded in the CoRE process). For questions or assistance, contact the UOHI IT Help Desk. Requests can also be escalated to the Director of IT Architecture and Planning.

4 Electronic "Secure File Transfer" Methods for Sending Documents to Potential/Existing Participants

The REB application must include the **secure file transfer** methods for sending/receiving documents to/from potential/existing participants, and the methods must align with respective institutional privacy policies.

TOH – Institutionally Approved Electronic Secure File Transfer Methods:

1. EPIC/MyChart (sending only)
   - ✓ Instructions for Use of EPIC/MyChart
2. Microsoft 365 SharePoint and OneDrive (sending and/or receiving)
   - ✓ Instructions for Use of Microsoft 365 SharePoint and OneDrive
3. The Ottawa Methods Centre Electronic Data Capture System (EDCS)

TOH IT and TOH Privacy offices **strongly discourages** sending encrypted emails or emails with password protected attachments to potential/existing participants as these are **not considered secure file transfer methods**.

UOHI – Institutionally Approved Electronic Secure File Transfer Methods:

1. EPIC/MyChart (sending only)
2. Encrypted Email (sending and/or receiving)

UOHI IT and UOHI Privacy offices permit UOHI research staff to send password protected documents to participants via email by selecting the "confidential" option which encrypts the entire email using **FortiMail**.

Note, prior to emailing TOH and UOHI patients, participant consent to communicate via email must be obtained.

5 Amendment Requirements for Changes Implemented in Response to the Pandemic

A section in the REB Memo released in April 2020 indicated that temporary changes during the pandemic did not require an Amendment submission to REB unless there was a risk to participants and/or data integrity. The instruction was to document the changes in a note to file as well as in the next continuing review form to the REB.

Moving forward, due to the ongoing nature of the pandemic, the REB's requirements have changed as the pandemic is no longer viewed at temporary. If your study is continuing during the pandemic and the changes implemented do not align with the REB approved file, protocol, consent and study documents, the changes can no longer be documented **only** in a note to file and in the continuing review form; **an amendment form must be submitted to REB if you haven't already**.

Study teams may proceed with the change that was documented in the note to file / continuing review form until the REB approval for the amendment has been received.

6 Reminder – Contingency Plan Reclassifications Require an Amendment

When requesting a change to the contingency plan classification from what is currently on file with the OHSN-REB, you must do the following:

- ✓ Complete the Updated Contingency Plan Reclassification Form and submit it via email to REBAdministration@ohri.ca.
  - If your ethics Board of Record (BOR) was the OHSN-REB, the form will be treated as an amendment and your study record will be updated.
  - If your BOR was another REB (i.e., REB application submitted to CTO, OCREB or CHEO REB), the form will be treated as an administrative change to your study, since the contingency question was included in the CRRF registration process.

For questions related to contingency plan re-classifications, please contact:

- **TOH:** OHRI Clinical Research Facilitators (CRFacilitators@ohri.ca).
- **UOHI:** Sharon Finlay, Manager, Clinical Research Compliance and Support Office (sfinlay@ottawaheart.ca)

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REB Process in Reviewing Quality Improvement Projects

The REB Office will review Quality Improvement projects that meet the following criteria:

- ✓ Researcher is unsure if the project is research or quality improvement
- ✓ The project may/will evolve into research

If the criteria above is met, please submit a copy of the project protocol and the completed QI Checklist to REBAdministration@ohri.ca. The Chair will review to make the determination whether the project is quality improvement or research requiring ethics review; the results of the review will be communicated via email.

If you are certain your TOH project is quality improvement, the QI checklist does not need to be submitted to the REB for review; simply register the project via the TOH QI SharePoint site.

If you are certain your UOHI project is quality improvement, the QI checklist does not need to be submitted to the REB for review, simply register the project at the UOHI Quality Office at quality@ottawaheart.ca.

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Who needs to register their research project in the CRRF?

Research Administration relies on an electronic web-based application called the Clinical Research Registration Form (CRRF) for tracking all research being conducted by our researchers. All clinical research activity must be registered in the CRRF. Researchers/staff must access the CRRF through their own IRIS homepage.

Who needs to register their research project in the CRRF?

- All research involving human subjects (including data and samples) at TOH and UOHI or by the investigators/personnel
  - ✓ regardless of where the recruitment of participants, data collection and/or sample collection are/is taking place.
  - ✓ regardless of the Board of Record (e.g. OHSN-REB or CTO Stream).

See the Application and Submission Process tab of the OHSN-REB website for more information.

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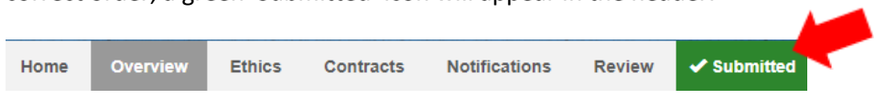
How to submit the Clinical Research Registration Form (CRRF)

All 3 tabs of the CRRF must be submitted individually and in the following order:
Notifications → Ethics →Contracts

Content may be entered and saved in any order as you work through the application, but the tabs must be *submitted* in a particular order. Once all three tabs have been submitted in the correct order, a green 'Submitted' icon will appear in the header:



If the green 'Submitted' icon is not present, your CRRF has NOT yet been submitted; have a look in the 'Overview' section to see which tabs still need to be submitted!

- ✓ Process for the Clinical Research Registration Form (CRRF)

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Technical Support

Contact IRIS Support at irissupport@ohri.zendesk.com:

- ✓ For technical assistance with the CRRF (i.e.: glitches, error messages, issues with saving, etc.)
- ✓ To request access to an Investigator's IRIS page/list of research studies (request must be sent by the Principal Investigator)

Contact TOH Helpdesk at 613-798-5555, x 14136:

For issues with TOH myHospital accounts (password reset, login issues, etc.)

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

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Ottawa Health Science Network Research Ethics Board (OHSN-REB)
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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.

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