OHSN-REB Top 10 Updates

20 October 2022

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

1 **NEW "Rescind Signature Request" for Initial Submission of Post Approval Form**

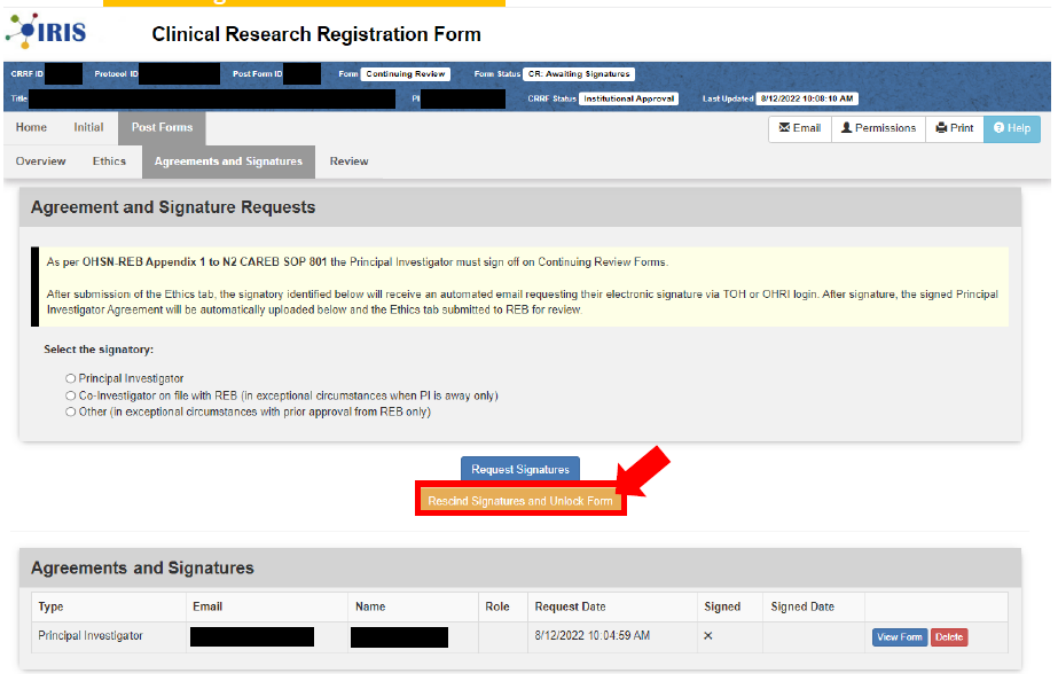
All of the REB's post approval forms (Continuing Review Form, Amendment Form, Reportable Event Form and Study Closure Form) have electronic sign offs built into them (as opposed to pen on paper signs off).

After a signature has been requested on the initial submission of an OHSN-REB's post approval form, the form status updates to *"Awaiting Signatures"* and all sections of the Ethics tab lock, preventing further edits.

If the signatory asks you to make changes to the post approval form prior to them signing, you are now able to rescind the signature request:

1. Open the post form submission and click on the '***Agreements and Signatures***' tab of the form:

2. Click the Rescind Signatures and Unlock Form button:



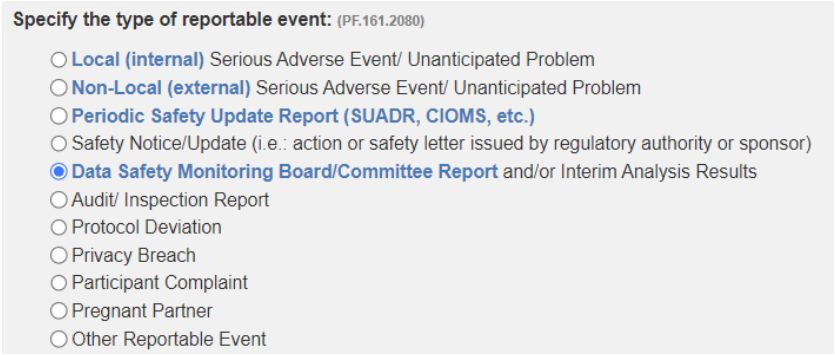
The signature request(s) will then be rescinded, and the form status will revert to "*Application New*" with all sections unlocked for editing. To submit the form to REB, a new signature request must be sent.

Note: The above only applies to the initial submission of an OHSN-REB post approval form, not subsequent submissions in response to an REB Review Letter (RL). Contact your Research Ethics Coordinator or REBAdministration@ohri.ca if changes need to be made to the form after the signature request has been sent for a subsequent submission responding to an REB RL.

2 **DSMB/C Meeting Summary Reports**

As per N2 CAREB SOP 404, researchers are responsible for submitting DSMB/C Meeting Summary Reports to the REB.

As indicated in the OHSN-REB Addendum, DSMB/C Meeting Summary Reports must be submitted to REB **within 15 calendar days** of receipt via the Reportable Event Form:



IMPORTANT: If the DSMB/C recommended changes, ensure it is clear in your submission if/how the changes impact participants at this site.

- For example, if the DSMB recommended that Arm 2 be paused due to drug toxicity concerns, indicate if any participants are in Arm 2 at our site, and if so, how many and what the notification and action plan is for them.

3 **Request for Use of Third-Party Technologies at TOH and UOHI Form**

The form applies to:

- Studies involving the use of third-party technologies (i.e.: technologies created and/or provided by someone outside of TOH/OHRI or UOHI/OHIRC).
    - For example:
        - ✓ Apps (downloaded or installed onto a smartphone or other device)
        - ✓ Web-based (online) portals
        - ✓ Cloud servers (e.g.: Drop box)
        - ✓ Commercial service providers (e.g.: Amazon Suite, Microsoft Azure)
        - ✓ Wearable Devices (e.g.: Fit Bit, smart watch)
        - ✓ Other devices (e.g.: cell phone, iPad, etc.)
- The institution's Privacy and IT offices must review and approve use of such technologies to ensure the privacy of research participants is being protected.

The form does NOT apply to:

- Industry or other academic site eCRF/EDC platforms that are solely used by research team members to send coded/de-identified, anonymized, or anonymous data to Industry or the lead academic site (e.g.: lead site's REDCap).

If you are unsure whether the form applies or not, consult with the REB, or the applicable TOH or UOHI personnel <u>in advance</u> of your ethics submission.

When the form is applicable, the following instructions should be followed for both **initial and amendment** applications:

1. A minimum of four weeks prior to REB submission:
   - Obtain the Request for Use of Third-Party Technologies Form from the REB website.
   - Complete the form and send to the applicable personnel identified on the form.
   - Wait for approval from all applicable parties. Note, this may take up to 4 weeks.
   - When receiving a message from the Privacy Office, or IT Services, you must answer promptly to avoid delays with the review process.

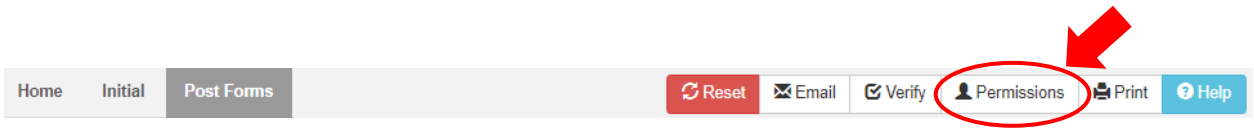
2. In the Notifications Tab of the CRRF, upload the form, signed by all applicable parties. If there is email correspondence with the IT and/or Privacy, upload the email correspondence as well. The REB must review the form and email correspondence prior to providing approvals.

3. Submit the Notifications, Ethics and Contracts Tabs of the CRRF.

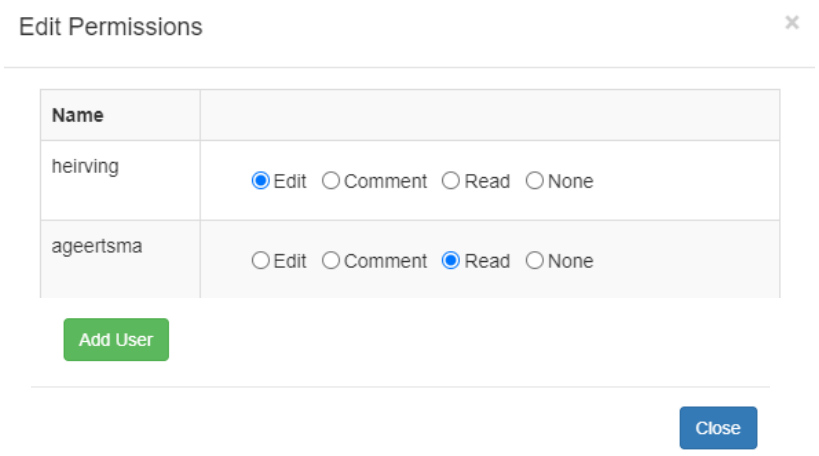
4

Clinical Research Registration Form (CRRF) "Permissions" for Initial Applications and Post Approval Forms

If you cannot access a CRRF and/or cannot see the purple comment bubbles or "unlocked" icons referenced in communication received from the REB, ask the Investigator or other research team member to edit the "Permissions" section of the CRRF:



Only those who have access to the PI's IRIS profile page and those listed in the "Permissions" section of the CRRF have access to the CRRF. Furthermore, access is defaulted to "***Read***" but study team members can only see the purple comment bubbles and "unlocked" icons if their permission is set to "***Edit***" or "***Comment***".



5

Reminder: All documents require a version date in the footer!

All documents uploaded into the REB application require a version date in the footer for tracking and auditing purposes.

6

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.

7

Reminder: Continuing Review Forms

- Use the Annotated Continuing Review Form that is posted on IRISGuide to assist you with your submission. **Please refer to the annotated form prior to submitting tickets to IRIS Support or contacting the REB Office.** The annotated form provides important instruction for older files that have had paper submissions to REB:
  - The tables requesting a list of Reportable Events and Amendments **only need to be completed with submissions for the review period** (i.e.: submissions in the last year, NOT submissions since initial approval).
  - The tables requesting Protocol and Consent Form versions only need to be completed with the **currently approved Protocol and Consent Form versions** (i.e.: all previous Protocol and Consent Form versions do NOT have to be listed).

- The purpose of the Continuing Review Form is to provide the REB with a summary of events over the last year; it is not designed to submit changes to the REB. Any changes to the study, including changes to the projected date of study completion, must be submitted to REB via an Amendment Form. Amendment Forms can be submitted in parallel to the Continuing Review Form.

- Continuing Review Forms must be received by the REB Office 40-50 days prior to the study expiry date. Tips for managing expiry dates:
  - ✓ At the time of initial and continuing review approval, Investigators/study teams should insert a 60-day reminder of study expiry into their Outlook calendar.
  - ✓ An automated 60-day email reminder is sent to the Investigator/study team. Note, this automated reminder will only send for studies where the one-time Intake Form has been submitted (Get your Intake Form submitted ASAP!).
  - ✓ The 'Ethics Notifications' section of your IRIS homepage shows your studies that are due to lapse in 90, 60 and 30 days, as well as those that are lapsed.

8

Reminder: Huddle Meetings

To help facilitate a timely REB review and improve submission to approval turnaround times, the REB Office is promoting remote MS Team huddles involving all applicable parties (study team, REB, Contracts, Facilitators, Privacy Office and/or IT).

The REB highly recommends that researchers request a Huddle **prior to** REB submission for complex studies.

To request a Huddle, email REBAdministration@ohri.ca with the following information:

- ✓ CRRF ID and / or protocol number, study title and acronym

- ✓ Names and emails of personnel to be invited to the huddle
- ✓ Summary of reason for Huddle request
- ✓ List of dates and times available
- ✓ Anticipated duration of huddle (e.g., 30, 60 or 90 minutes)

9 **Reminder: CHEO and OHSN REB Harmonized REB Review Process**

Reminder that studies falling under the jurisdiction of both CHEO and OHSN REB (e.g.: 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.

What is the process?

STEP 1: Study teams must complete a REDCap Survey: TOH & CHEO REB Harmonization

STEP 2: The Survey will be reviewed to determine the following, which will need to be submitted simultaneously:

a) the review system (ROMEO at CHEO/CHEO RI, IRIS at TOH/OHRI or CTO Stream) to be used for ethics review which will be used for the life of the study
and
b) the system for study registration (TOH/OHRI Clinical Research Registration Form (CRRF) via IRIS and/or CHEO RI Smart Start process via REDCap).

The decision and further instructions will be communicated to you via email.

10 **Technical Support**

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

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

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

- ✓ For technical assistance with the CRRF (e.g.: 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)

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