OHSN-REB TOP 10

OCTOBER 19,2022

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

1

REB Staffing Update

Back in June, there were a couple of staffing changes in the REB office:

- **Maria Caissy** joined our team as the new **REB Administration Assistant**. You've likely heard from Maria if you've emailed the REBAdministration@ohri.ca inbox in the last couple of months.

- **Isabelle Woodward** joined our team as a **Research Ethics Coordinator**. Isabelle is currently reviewing new secondary use applications, Reportable Event Forms, and certain Amendment Forms. Isabelle can be reached at iwoodward@ohri.ca.

2

Reminder: Updated Addenda to N2 CAREB SOPs

The OHSN-REB Addenda to the N2 CAREB SOPs were updated in January 2022. You can find the updated Addenda in the "SOPs" tab of the OHSN-REB website **or** the "Policy and Procedures" section of the OHSN-REB page on IRISGuide. All applications should review the REB SOPs and addenda for reporting expectations and timelines.

3

CRRF/IRIS Security Timeout

IRIS has a one-hour security session timeout. If no action is taken (e.g.: click a button, change an option, etc.) within the hour, the current session ends, and any further actions **are not saved** to the database. **Any action taken restarts the one-hour timeout**.

During normal use the timeout is never reached, and most users will never encounter it. There are two cases that have been causing issues with the timeout:

Case 1: Leaving a page open in the browser for an extended period of time

- If you have left the page open either by **leaving it open in another browser tab** or **leaving the computer**, the session will timeout at 1 hour. When you return to the page, you will be able

to interact with the page but **any changes you make will not be saved**.

- **Solution:** When returning to a page, **refresh the page** before beginning your work.

Case 2: Typing in a large amount of text into a single text box

- Sometimes a large amount of text is required for a single text box. (Tab 2 of ethics in the initial CRRF application) When inputting the text into a text box, it is not updated until the **focus** leaves the text box. If the **cursor** does not leave the text box, the timeout will trigger even if you are still inputting text. The action is registered when the **focus** leaves the text box.

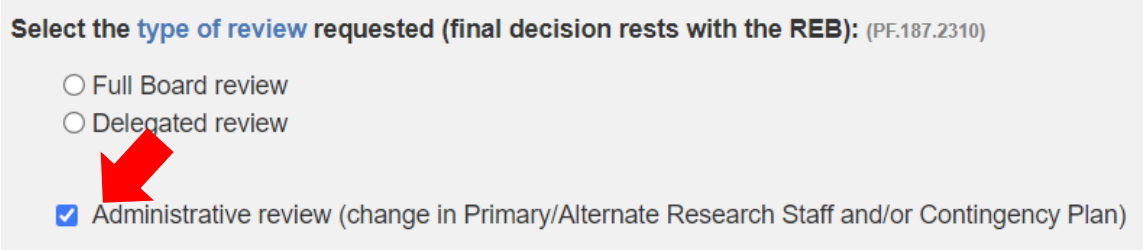
- **Solution:**
  a) Use a **Word document** to create the text then **copy and paste** it into the text box.
  b) Periodically change the **focus**. (**Pressing "Tab"** or **clicking anywhere on the page other than the text box** will change the focus)

If you have any questions or are experiencing any issues with the security timeout, please contact IRIS Support directly at irissupport@ohri.zendesk.com

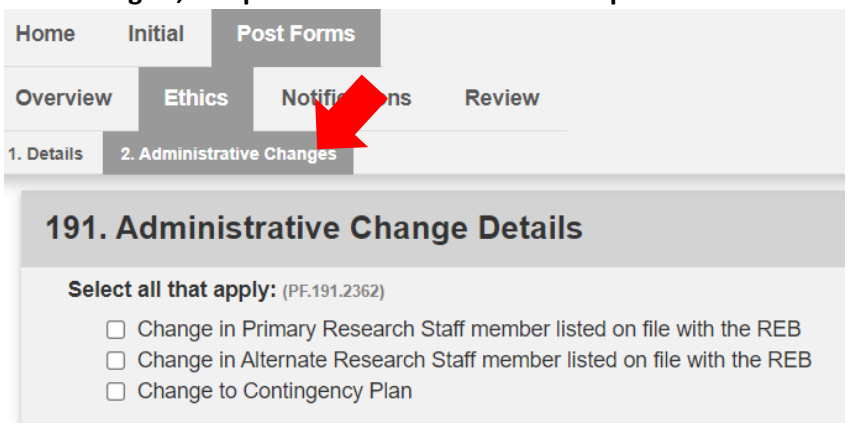
4 **How to change Primary and/or Alternate Research Staff on file with REB**

An **Amendment Form** must be submitted to change the Primary and/or Alternate Research Staff Member(s) on file with the REB.

In Ethics Tab 1 of the Amendment Form, select "Administrative Review":



After doing so, complete the additional tab that opens – Ethics Tab 2: Administrative Changes:



5 **Clarification: Initial REB Application Department/Division Head Signature Requirements**

TOH Department/Division Head:

- Obtain the signature of the **TOH Department Head** unless the Department is Medicine or Surgery, in which case the Division Head's signature can be obtained (if the Division Head has a conflict, obtain the Department Head's sign off).
- If the Department Head is in conflict with the Protocol (for example, they are the PI or Co-I of the study), Dr. Bill Cameron's sign off should be obtained.
- For the Clinical Epidemiology Program (CEP), obtain the signature of the Department Approver, which is currently Dr. Dean Fergusson

UOHI Department/Division Head:

- Obtain the signature of the **UOHI Division Head**.
- If the Division Head is in conflict with the Protocol (for example, they are the PI or Co-I of the study), Dr. Peter Liu, Chief Scientific Officer (CSO), should sign off. If Dr.Liu is also in conflict, Dr. Thierry Mesana, Chief Executive Officer (CEO), should sign off.

OHSN-REB Appendix 1 and Appendix 2 to N2 CAREB SOP 801, which outline signature requirements, have been updated for clarity.

6 **Reminder: One-Time Intake Form**

The One-Time Intake Form for each study was due June 1st. If you have not already, please complete and submit the One-Time Intake Forms ASAP! This will ensure that the current study team members listed on file will receive the automated emails generated by the system, including the 60-day reminder of ethics expiry.

See the Applicant User Guide: CRRF Post Form Navigation Tool for step by step instructions.

7 **Reminder: Live URL for Surveys/Questionnaires**

For studies administering surveys/questionnaires electronically (e.g.: via MS Forms, REDCap, LimeSurvey), a Word document (or PDF if it is a validated survey/questionnaire) must be uploaded into the REB application.

- If the **live URL is available** prior to REB approval, it too must be provided.
- If the **live URL is not available** prior to REB approval, it can be provided after REB approval via an Amendment Form, but prior to use. URLs must be approved by the REB!

The Word/PDF must correspond with the live URL; prior to submission to REB, study teams must verify this. If they do not correspond, REB approval cannot be granted.

8 **Reminder: Updates to old Consent Forms**

For studies that are still open to recruitment: If the study's consent form has not been revised in the last 5 years, update the consent form to reflect the current OHSN-REB consent form template and submit an Amendment to the REB.

9 **Reminder: PI/Study Team Translations**

All patient facing documents that are translated by the Principal Investigator (PI)/Study Team require verification by OHRI French Translation Services.

This includes applications being submitted to an external Board of Record (e.g.: via CTO Stream). If the PI/Study team is translating, the translated documents must be verified by OHRI French Translation Services before they are submitted to the Board of Record for review/approval.

See the Applicant User Guide: Translation Process for step by step instructions.

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 and/or REB Manager, please contact REBAdministration@ohri.ca