

OHSN-REB TOP 10

JUNE 7TH, 2022



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

1

Electronic Post Approval Forms were Launched in IRIS on March 15th

The OHSN-REB's electronic post approval forms were launched in the local IRIS system on March 15th.

The REB Office held a presentation on March 15th to introduce the post approval forms, which included details on how to access & navigate the electronic post approval forms (i.e., amendments, reportable events, continuing review, and study closure forms).

The presentation and supporting documents are posted on [IRISGuide](#) in the Templates, Forms and Guidelines section.

Presentations:

- [REB Education Session PowerPoint Slides: Electronic Post Approval Forms, March 15, 2022](#)
- [REB Education Session Recording: Electronic Post Approval Forms, March 15, 2022](#)

The following tools should be used to assist you with navigating the electronic system:

- [Applicant User Guide: CRRF Post Form Navigation Tool](#)
- [Applicant User Guide: CRRF Translation Process](#)
- [Applicant User Guide: Responding to a Signature Request](#)

PDFs of the Electronic Forms: The annotated forms should be used as a reference prior to sending any tickets to the IRIS Support Team and REB Office. The annotated forms are designed to assist you with your submission.

- [Annotated Amendment Form](#)
- [Annotated Reportable Event Form](#)
- [Annotated Continuing Review Form](#)
- [Annotated Study Closure Form](#)

IMPORTANT: The One-Time Intake Form for each study submission 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.

If the Intake Form has not been submitted, the automated emails, including the 60-day reminder of study expiry, may **not** send to the correct study personnel on file.

2

Updated Research Ethics Coordinator Case Management

Please note, we are currently short staffed which may cause temporary delays.

We are pleased to announce two new hires in the REB Office:

- Maria Caissy, Research Administrative Assistant, starting Wednesday June 8th
- Isabelle Woodward, Research Ethics Coordinator, starting June 13th.

A new Case Management list was put into effect May 1, 2022. You can find the new list in the '[Contacts](#)' tab of the OHSN-REB website or in the '[Contact Us](#)' section of IRISGuide:

OHSN-REB Office Contacts

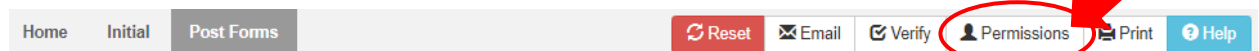
Question or concerns about a specific study should be directed to your assigned Research Ethics Coordinator. Please review the [Case Management](#) document to identify the Research Ethics Coordinator responsible for your area.

If you have any questions about your ethics application, please contact the Research Ethics Coordinator assigned to your department/division.

3

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".

Edit Permissions



Name	
heirving	<input checked="" type="radio"/> Edit <input type="radio"/> Comment <input type="radio"/> Read <input type="radio"/> None
ageertsma	<input type="radio"/> Edit <input type="radio"/> Comment <input checked="" type="radio"/> Read <input type="radio"/> None

Add User

Close

4

Electronic Sign Offs in Post Approval Forms

The signatory identified in the 'Agreements and Signatures' tab of a post approval form must use their **TOH/OHRI login** (i.e.: TOH/OHRI email address and password) in order to apply their electronic signature.

Troubleshooting:

- ✓ For password resets, contact the TOH Helpdesk at 613-798-5555, x 14136.
- ✓ If the Principal Investigator does not have a TOH/OHRI login, please email REBAdministration@ohri.ca with the Post Form ID and Principal Investigator name.
- ✓ For step-by-step instructions on how to sign using your TOH/OHRI login, see the [Applicant User Guide: Responding to a Signature Request](#) located on the IRISGuide.

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Continuing Review Form Reminders

- 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 any tickets to IRIS Support Team 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.

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File Uploader Reminder: Follow the REB's Naming Conventions!

When uploading documents into the CRRF, ensure the file name follows the naming convention provided in the file uploader (see **yellow** highlight and examples below).

This is important as the name given to the file will auto pull into the REB's approval letter.

Study Protocol (must be the most current protocol version): (E1.5.19)

File Uploader

Please select a file to upload (each file can be **no larger than 10 MB**) Permitted file types include extensions .doc, .docx, .xls, .xlsx, .pdf, .jpg, .jpeg, .bmp, .png, .gif, .txt, .ppt, .pptx.

The following naming convention MUST be used: Protocol. For example, "Protocol". The version date of the document must be selected from the Version Date calendar.

No file chosen

Non-participant facing documents:

- **If new:** <Document Name>
For example, "Protocol " or "Investigator's Brochure for MRTX849".
- **If revised:** Tracked <Document Name> and Clean Revised <Document Name>
For example:
"Tracked Protocol" and "Clean Revised Protocol"
"Tracked Investigator's Brochure for MRTX849" and "Clean Revised Investigator's Brochure for MRTX849".

Participant facing documents:

- **If new:** <English/French> <Document Name>
For example, "English Main Consent Form" or "English Recruitment Poster"
- **If revised:** Tracked <English/French> <Document Name> and Clean Revised <English/French> <Document Name>
For example:
"Tracked English Main Consent Form" and "Clean Revised English Main Consent Form"
"Tracked English Recruitment Poster" and "Clean Revised English Recruitment Poster"

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File Uploader Reminder: Select the Version Date!

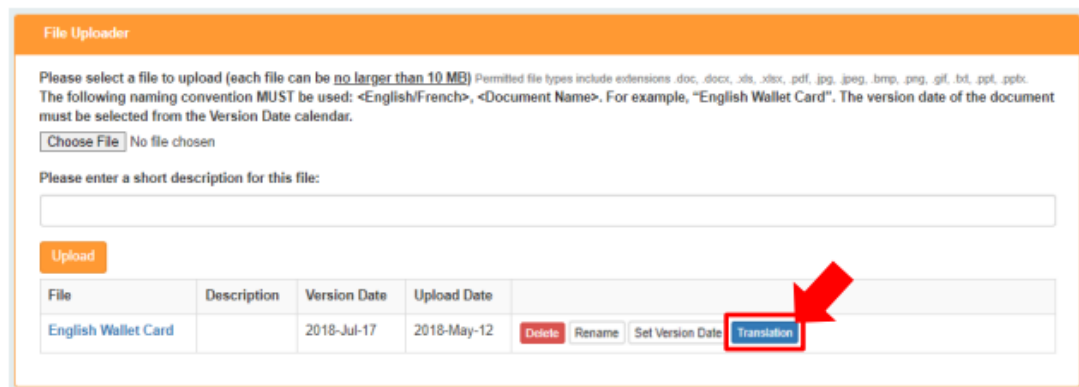
All documents uploaded into the CRRF require a version date for tracking and auditing purposes. The version date of each uploaded document must be selected from the version date calendar using the “Set Version Date” button.

Note, original validated questionnaires/tools must not be altered; therefore, if a version date does not exist on the original validated document, please do not add a version date.

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File Uploader Reminder: Click the ‘Translation’ Button!

In accordance with The Ottawa Hospital (TOH) and University of Ottawa Heart Institute (UOHI) policies on bilingualism, all English patient facing documents must be translated into French. Prior to submission of your application, select the **Translation** button of each upload & identify the respective translator:



The screenshot shows the 'File Uploader' interface. At the top, it says 'Please select a file to upload (each file can be no larger than 10 MB)'. Below this is a 'Choose File' button and the text 'No file chosen'. There is a text input field for 'Please enter a short description for this file:'. Below that is an 'Upload' button. At the bottom, there is a table with the following columns: File, Description, Version Date, Upload Date, and a row of action buttons: Delete, Rename, Set Version Date, and Translation. The 'Translation' button is highlighted with a red box and a red arrow points to it.

File	Description	Version Date	Upload Date	
English Wallet Card		2018-Jul-17	2018-May-12	Delete Rename Set Version Date Translation

The REB requires this information in order to proceed with approval; if this information is not present, it will cause delays in obtaining your approval.

The [Applicant User Guide: Translation Process](#) is available on [IRISGuide](#)!

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File Uploader Reminders

- After an application has been submitted to the REB, do not delete any of the uploaded documents unless specifically instructed to do so by the REB. All uploads must remain for auditing purposes.
- For revised documents, a tracked copy showing the changes to the version currently approved by REB, as well as a clean final copy, are required.

- The tracked copy must include the text change to the version date, as the REB must ensure the changes were made to the currently approved version.
For example: ~~January 15, 2020~~ March 7, 2021
- The clean copy must have all changes accepted and all comments deleted.

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**