

OHSN-REB TOP NEWS

Monday March 7th, 2022



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

NEW Electronic Post Approval Forms to Launch in IRIS Tuesday March 15th, 2022

The REB is pleased to announce the launch of the electronic post approval forms in the local IRIS REB application on Tuesday March 15, 2022. In addition to the initial application, amendments, reportable events, continuing review, and study closure forms will also be available in IRIS electronically.

What does this mean for you?

As of March 15th, you will be able to submit your post approval submission(s) (amendments, reportable events, continuing reviews, and study closures) electronically in the IRIS Clinical Research Registration Form (CRRF), instead of completing the Word document versions found on the OHSN-REB website or IRISGuide and emailing to the REB Office.

How can I learn about this new process for submitting post approval forms electronically in the IRIS Clinical Research Registration Form (CRRF)?

- **Attend one of the REB education sessions on March 15th which will be held remotely through MS Teams from 9:00 am to 11:00 am and 1:00 pm to 3:00 pm.**
 - We strongly encourage attending one of the sessions as you will have opportunity to ask questions. For those not able to attend, the sessions will be recorded.

How to submit a CRRF post approval form in IRIS:

1. Attend one of the REB education sessions on March 15th/ watch the recorded presentation and review the 'Applicant User Guide: CRRF Post Form Navigation Tool' for step-by-step instructions.
2. **Submit an "Intake Form":**

The intake form is a one-time form which will open the portal for you to start submitting post approval forms. Its purpose is to create a CRRF application for studies that do not have one, or to update the homepage of existing CRRF applications.

The intake form can be submitted anytime after March 15th, either by itself or at same time of your next amendment, reportable event, or continuing review form. If you do not plan to submit a post approval form prior to June 1st, the intake form should be submitted by itself as it will ensure automated emails are sent to current study personnel. For example, automated email reminders that your study will expire in 60 days.

3. **Submit a Post Approval Form:**

Once the intake form has been submitted you will be able to create post approval forms electronically via a new "Post Forms" tab in the study's CRRF.

Which studies do the intake form and electronic post approval forms apply to?

The new electronic post approval forms apply to **ALL** studies reviewed by OHSN-REB!

This includes those with initial REB applications submitted in:

- ✓ The new IRIS REB application launched February 2018 - CRRF (the Clinical Research Registration Form)
- ✓ The old IRIS REB application launched in 2012 up until the launch of the updated application in February 2018
- ✓ Old hard copy studies that were initially submitted prior to the electronic launch in 2012
- ✗ The intake form will not be required for REB applications that receive REB approval after March 15th.

What should I do if I *only* need to close my study and no further amendments, reportable events or continuing reviews are required?

If your study is complete and only in analysis phase, and you do not anticipate accessing the medical charts anymore, you may want to consider closing your study using the paper study closure form instead of submitting electronically in IRIS but do this promptly because this will only be offered for a limited time!

The REB office will continue to accept paper copies of study closure forms via email at REBAdministration@ohri.ca up until June 1st, 2022. In these cases, an intake form will not need to be completed.

Are the electronic post approval forms available for studies registered in the Clinical Research Registration Form (CRRF) and reviewed by an external Board of Record?

No, the electronic post approval forms are not available for studies registered in the CRRF yet. These will be launched in late spring/summer 2022. Registered studies consist of CTO Stream submissions, and ROMEO submissions under the OHSN/CHEO Harmonization agreement.

The registration post approval forms are designed to report information to the institutions (OHRI & OHIRC), and provide the following information:

- Updated protocols
- Allow for updated participant facing documents to be sent to translation services
- Local reportable events
- Update the registration at time of continuing review
- Update the registration at time of study closure

We would like to thank the Business Systems Integration Team (BSIT), REB Office for their dedication to building the electronic post approval forms in IRIS. We would also like to thank research staff at OHRI and UOHI who participated in the testing phase.