

# OHSN-REB TOP 10

THURSDAY MARCH 10<sup>TH</sup>, 2022



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

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## **NEW** Electronic Post Approval Forms to Launch in IRIS Tuesday March 15<sup>th</sup>, 2022

**UPDATE TO MESSAGE BELOW:** The post approval submission will be live as of Tuesday March 15<sup>th</sup>, 2022. We will allow word document/email submissions until March 31<sup>st</sup>. We recognized that it is the season for Spring breaks and many staff members are taking vacation. If you are already working on a word document submission, we will allow the submission until March 31<sup>st</sup>!

### **The announcement below was sent on Monday March 7<sup>th</sup>, 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 15<sup>th</sup>, 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 15<sup>th</sup> 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 15<sup>th</sup>/ 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 15<sup>th</sup>, 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 1<sup>st</sup>, 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 15<sup>th</sup>.

#### 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 the need for further access to the health records, you may want to consider closing your study using the Word version of the 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 Word version copies of study closure forms via email at [REBAdministration@ohri.ca](mailto:REBAdministration@ohri.ca) up until June 1<sup>st</sup>, 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.

**2**

**[Update Third Party Request Form can be found on OHSN-REB Website and IRISGuide & has been included in the CRRF Notification Tab](#)**

If you plan to use third party technologies at TOH or UOHI a completed "[Request for Use of Third-Party Technologies at TOH or UOHI](#)" form must be submitted to:

- **For TOH:** Mike Hendley ([mhendley@ohri.ca](mailto:mhendley@ohri.ca)) and Anne Lavigne ([anlavigne@toh.ca](mailto:anlavigne@toh.ca))
- **For UOHI:** Pierre Lefebvre ([plefebvre@ottawaheart.ca](mailto:plefebvre@ottawaheart.ca)) and Jennifer Lajeunesse ([jlajeunesse@ottawaheart.ca](mailto:jlajeunesse@ottawaheart.ca))

Examples of third-party technologies include but are not limited to:

- ✓ 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.)

**NEW** A copy of this form, signed by the institution's IT and Privacy Office, will need to be uploaded into the **Notifications tab** of the Clinical Research Registration Form.

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**[Updated Consent Forms Available on OHSN-REB Website and IRISGuide](#)**

The following consent form templates have been updated:

- Main Clinical Trial/Study Informed Consent Form
- Minimal Risk Informed Consent Form
- Optional Informed Consent Form

These consent forms have been updated to align with regulatory requirements. Each consent form template posted is accompanied by a summary document explaining the change.

If your study is subject to US regulations, please review the new template as the consent form has been updated to include a summary at the beginning. This is a requirement for all studies subject to US regulations and an amendment should be submitted to include this update if your study is actively recruiting.

The updated **translated** consent form templates will be available 1<sup>st</sup> week of April.

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#### NEW REB Review Process for Consents that have been Approved for 5 years or >

If an update to the consent form has not occurred within the last 5 years, we ask all applicants to update their consent form to reflect the new template by submitting an amendment to the REB.

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#### Reminder: Institutional Approval is required prior to starting your study

Institutional approval consists of completion of notifications, ethics and contracts tab in the Clinical Research Registration Form (CRRF). The tabs must be submitted in the following order:

1. Notification tab
2. Ethics tab
3. Contracts Tab

You may work on all three tabs simultaneously, however, the submission must occur in this order!

The Contracts Tab must be submitted immediately after the Ethics Tab whether your study requires a contract or not to avoid delays in receiving institutional approval. Prior to submitting the contracts tab, please ensure to re-review the contracts tab to ensure it is consistent with the information in the ethics tab.

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#### Update for CTO Applications

For CTO studies, the main clinical trials and observational informed consent form (ICF) templates have been updated on the Clinical Trials Ontario website <https://www.ctontario.ca/>.

For new CTO submissions, please ensure you use the current updated ICF template.

For studies already approved and actively recruiting, it is recommended that the ICF is updated to the current ICF template as most of the changes to the template were for regulatory requirements. For example, if your study is subject to US regulations, and your study is actively recruiting, please update your consent form via an amendment to include the summary document required by US regulation.

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#### Reminder of Who Can Sign-Off on CTO Submissions

Any new application (a new initial application, a new Amendment, a new Continuing Review, etc.) **must be signed by the Principal Investigator** in CTO Stream. CTO permits subsequent correspondence related to the submission (revisions/corrections) to be signed by a delegate. Often times, the REB must return applications (especially Continuing Review Forms) to the study team solely because the PI's signature is required but wasn't obtained.

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#### Update for All Documents that Require Translation

When English versions of REB approved documents require translation or verification by any translation service, please provide the word version of the document rather than PDF versions as it is difficult for translators to translate from PDF documents.

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### Reminder for Device Studies

The REB office encourages investigators and study teams to meet with an OHRI Clinical Research Facilitator or the UOHI Clinical Research and Compliance Office for support in OHRI/OHRC sponsored device studies prior to submitting your initial REB application.

During the OHRI Clinical Research Week in October 2021, Yan Yu He, OHRI Facilitator, presented a presentation for Medical Device Trials subject to Regulations. We highly recommend watching the video of the presentation by clicking on the link below. After watching the recording, we suggest you document this training if your clinical trials involve investigational medical devices, since Health Canada looks for evidence of training on the applicable regulations.

 [Regulated Trials Involving Medical Devices, Software, and Apps-20211020\\_093017-Meeting Recording.mp4](#)

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### Reminder to OHRI Staff for SharePoint Files

Documents saved on TOH/OHRI SharePoint may include study files containing personal information (PI) and/or personal health information (PHI) **and/or** study files not containing such information.

#### **If a document saved on SharePoint contains PI/PHI (examples, signed ICF, source health records or certain research notes for source data verification)**

- Such files can only be shared via the [OHRI 3<sup>rd</sup> party sharing folder](#) that's created by each research group's Super User(s). This gives external staff restricted view access only (i.e., external staff cannot copy, download, or edit any SharePoint file containing PII/PHI). This approach will permit appropriate physical, technical and administrative control over the process to help ensure that the privacy of research participants is always protected.
- Research teams that need access to the OHRI 3<sup>rd</sup> party sharing folder for this purpose must contact their group-specific Super User(s). If there is no Super User for your group, please reach out to [CRFacilitators@ohri.ca](mailto:CRFacilitators@ohri.ca) to set up a date/time for Super User training.

#### **If a document saved on SharePoint does not contain PI/PHI (examples, Study protocol, ICF template, IB/PM, CRF template, documents with all PII/PHI redacted)**

- SharePoint files can be shared with external staff through a SharePoint group/folder, and where applicable, as permitted by study-specific approved REB application and/or data sharing agreements.
- Approval from OHRI Clinical Research Administration is not required for sharing these files with external staff.

**If you would like to request a virtual huddle meeting with the Chair or REB Manager, please contact [REBAdministration@toh.ca](mailto:REBAdministration@toh.ca)**