OHSN-REB Top 10 Updates

January 11th, 2023

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

1

COMING SOON - REB Education Catalogue

Portions of the REB's Education Catalogue are set to be released on IRISGuide next week, including:

- ✓ Protocol Template for Secondary Use Study
- ✓ Protocol Template for Delegated Prospective Study
- ✓ REB Application Guidance for Secondary Use Applications
- ✓ REB Application Guidance for Delegated, Prospective Applications

Stay tuned – a separate announcement will be sent out once they are available on IRISGuide.

Additional educational materials are in the works and will be added as they become available. If you have suggestions for topics you'd like to see covered, please email REBAdministration@ohri.ca.

2

NEW – Funding Tab of Local OHSN-REB Ethics Application in IRIS

If your study is Investigator-Initiated by a TOH/OHRI or UOHI/OHIRC Investigator, **two** study budgets must now be uploaded into Ethics Tab 12: Funding:

- Full study budget (for all sites) NEW
- Local itemized study budget (for this site only)

ALERT! This requirement applies to ethics applications in the local IRIS system only. This does NOT apply to applications submitted through CTO Stream, as the CTO Stream system is transparent, and all participating sites have access to all study documents that are uploaded into the Provincial Initial Application; you may not want all participating sites to have access to your full study budget.

3

NEW – Electronic Signatures for Initial Ethics & Registration Applications, Effective January 9, 2023

Effective **Monday, January 9, 2023**, all new initial ethics, and registration applications **submitted** in IRIS will include **electronic** sign offs.

What does this mean?

- ✓ For **ethics** applications, the **Principal Investigator**, **Co-Investigator** (if one is listed), and **Department/Division Head** listed in Ethics Tab 1 of the application will receive an automated email asking them to sign electronically using their TOH/OHRI login (no more paper signatures!).

- ✓ For **registration** applications, the **Principal Investigator** listed in Ethics Tab 1 of the application will receive an automated email asking them to sign electronically using their TOH/OHRI login (no more paper signature!).

- ✓ The Ethics Tab of the CRRF will only be submitted to REB once **ALL** applicable electronic sign offs have been obtained.
    - **ALERT!** Be mindful of this when submitting applications for Full Board review as **ALL** signatures must be obtained **prior to** the REB's Full Board submission deadline in order for the application to be received by the REB by the deadline.

Note, there is no change to the order the three tabs of the CRRF must be submitted; it remains:
1. Notifications Tab → **2.** Ethics Tab → **3.** Contracts Tab (Contracts tab can still be submitted if electronic signatures are pending in the Ethics tab).

4

REMINDER – Electronic Signature when Responding to an REB Review Letter (Ethics and Registration Applications)

Prior to issuing a Review Letter, the REB assesses the Review Letter items to determine if the Principal Investigator's (PI) signature is required on the point-by-point response letter (i.e.: is PI oversight is required).

- If PI signature is required, this will be clearly indicated in the Review Letter.
- If PI signature is **not** required, a delegate may sign.

The application requires an electronic signature (PI or delegate) in order to be re-submitted to the REB; if an electronic signature is not obtained, the application will not be received by the REB.

5

REMINDER – UPDATED Initial REB Review Fee & NEW Major Amendment Review Fee, Effective January 1, 2023

As communicated in a memo on November 3, 2022, the OHSN-REB implemented the following **January 1, 2023**:

- ✓ An increase to the **initial review fee** from **$3000 to $3500** for new industry-sponsored studies
- ✓ A **$500** for major amendments submitted for new industry-sponsored studies
- ✓ A **$2500** for major amendments submitted for adaptive, basket, umbrella and platform trials meeting one of the fee criteria outlined above when the amendment involves the addition of new protocols, drugs, consent forms and/or other substantive changes.

Study teams should include these new fees in contract negotiations.

6

REMINDER – Investigator-Initiated Trials where OHRI is the Sponsor

For **investigator-initiated drug**, **natural health product** and **medical device** trials where **OHRI is the sponsor,** reach out to the OHRI Clinical Research Facilitators **prior to** submission of the CTA/ITA application to Health Canada, and **prior to** REB application submission.

The Clinical Research Administration team must review all study related documentation from a regulatory perspective before approving the CTA/ITA application for institutional signature.

For more information, please see:

- N2 SOP 018 – OHRI Addendum Health Canada Application for **Drugs** Review/Approval Process
- N2 SOP 023 – OHRI Addendum Health Canada Application for **Natural Health Product**s Review/Approval Process
- N2 SOP 024 – OHRI Addendum Health Canada Application for **Medical Devices** Review/Approval Process

REMINDER – Investigator-Initiated Trials where OHIRC is the Sponsor

For regulated, investigated-initiated research where OHIRC is the sponsor, please email the Office of Clinical Research and Compliance prior to submitting the application to Health Canada. The clinical research facilitator will review and initiate for the institutional signature process.

7

Principal Investigator Leaving the Institution

If the Principal Investigator (PI) is leaving the institution, all their REB files must be either closed, **or** transferred over to another Investigator **prior to** their departure.

It is the PI's responsibility to always ensure participant oversight. In addition, after a PI has left the institution, they will not be able to provide their electronic sign off on the Amendment or Study Closure Form, as their TOH/OHRI and UOHI/OHIRC login will be terminated.

8

REB Application Tip - Acronyms

In the Research Ethics Board (REB) application, introduce every acronym **before** using it. When using the term for the first time, put the acronym in parentheses. Acronyms should only be used if it appears several times in the same response to the REB.

9

TOH/UOHI Department and Division Head List

The initial REB application requests Department/Division Head sign off. Did you know that TOH/UOHI maintains a list of the Department/Division Heads, including their Administrative Assistant contacts?

It is available on myHospital here (TOH/OHRI) or on the UOHI Heart Hub (UOHI/OHIRC).

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 or REB Manager, please contact REBAdministration@ohri.ca