





## Ottawa Health Science Network Research Ethics Board/ Conseil d'éthique de la recherche du réseau de science de la santé d'Ottawa

## February 12, 2016

## ANNOUNCEMENT - Please read carefully Expired Study Status

It is the Principal Investigator's responsibility to ensure that the study remains in compliance and the ethical approval does not lapse for a study. It is the REB's mandate to re-evaluate an ongoing study on at least an annual basis. Investigators and research staff may easily follow their study expiry dates by looking at the "Ethics Ticker" in IRIS found at https://iris/.

The **Ethics Ticker**, located at the top, right-hand corner of the investigator's **IRIS** home page (picture below), displays studies that have expired, or are set to expire in 30, 60, or 90 days. Investigators must recognize that there may be issues arising from the submitted information causing delays in approving renewals. **As such, OHSN-REB must receive the annual renewal report form in hardcopy no later than 30 days prior to the expiry date.** 

Termination reports must be submitted for completed projects. Expired status for any study in the Ethics Ticker is unacceptable and must be prevented. View the Ethics Ticker on a routine basis to assist in the management of expiry dates. Any studies showing an expired status should be immediately addressed.

## **Consequences of study expiration:**

- A warning or suspension letter notice will be issued to the Researcher.
- When suspended, the Researcher must suspend all research activities as specified by the REB. REB Office Personnel will follow-up with the Researcher to ensure that the application for continuing review is submitted immediately.
- Project cost centre may be frozen, and expenses/transfers/payments will not be processed until continuing review has been submitted, which may impact payroll.
- Participants recruited during expired status the Chair/Vice-Chair of the REB may rule that the participants must be withdrawn and data may not be used.
- You may encounter issues when seeking to publish studies that experienced lapsed ethics approval.
- The REB may choose to close expired studies and request a new application be submitted.
- All lapses in approval will be documented in the REB's study file as well as in the REB letter renewing the study (visible to monitors, auditors, and inspectors).

Should your study expire, the **REB will require the following information**:

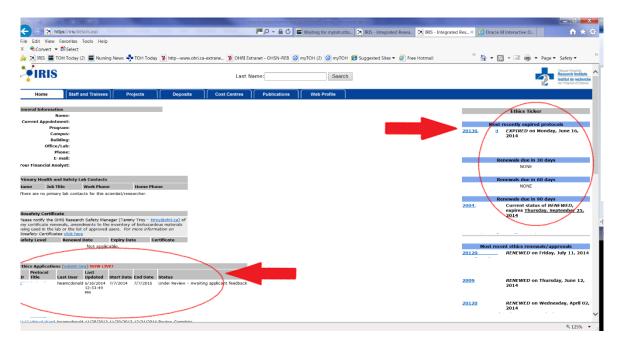
- Confirmation that all research activity has been suspended (unless granted approval to continue study visits for safety concerns).
- A detailed explanation for why the study's ethical approval lapsed.
- A corrective action plan to ensure that ethical approval does not lapse again.

Repeat offenders will be asked to meet with the Chair/Vice-Chair of the REB.

Please pay attention to both the <u>Ethics Ticker</u> and the <u>Ethics Applications</u> areas of your IRIS homepage.

The Ethics Applications area (your work-in-progress area), located on the left-hand side, displays electronic applications you have submitted with the current status of your application showing as follows:

- New The review process has not started
- Under Review Protocol Officer Review is underway
- Under Review Awaiting Applicant Feedback The REB is waiting for your response/revisions
- Forwarded for Review (Full Board; Delegated) The application has been either placed on the agenda for the next meeting or is with one of the Chairs for review
- Review Complete The REB has completed their review and the study has been approved (or terminated if you have chosen not to go forward with project)



We thank you for your collaboration.

Sincerely,

Raphael Saginur, MD

Chair, Ottawa Health Science Network Research Ethics Board