

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

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<http://www.ohri.ca/ohsn-reb>

March 23rd, 2016

Renewal Process for Studies Reviewed at a Full Board Meeting

Your study's continuing review (annual renewal) may require review at a convened full Board meeting.

Does your project fall into either of these categories?

1. If your protocol was originally reviewed at a full Board meeting and there has been an **amendment submitted during the year that increased the level of risk to the study participants**, then the continuing review report and supporting documentation must be reviewed at a full Board meeting.
2. Is your study **subject to the US Code of Federal Regulations**?
 - a) The study is using an investigational product, or a marketed product outside of its approved marketing conditions, for example, under an IND or IDE in the US.
OR
 - b) The study is sponsored by or is using a product from a U.S. based company.
OR
 - c) Investigators who receive an award through grant, contract, or cooperative agreement from the Department of Health and Human Services.

If your protocol involves any of the three conditions above, was initially reviewed at a full Board meeting, and participants are still undergoing protocol mandated procedures then your Continuing Review (annual renewal report) **must be reviewed at a full Board meeting**.

Your protocol's renewal may be reviewed in a delegated fashion when **all** of the follow apply:

- a) the research is permanently closed to the enrolment of new subjects;
- b) all subjects have completed all research-related interventions; **and**
- c) the research remains active only for long-term follow-up of subjects

What to do:

1. Clearly indicate on the report that you are requesting review by the full Board;
2. Annual renewal report forms must be received in hardcopy **no later than 30 days prior to your expiration date.**

It is the Principal Investigator's responsibility to ensure that the study remains in compliance and the ethical approval does not lapse. Investigators and research staff may easily follow their study expiry dates by looking at the "**Ethics Ticker**" in IRIS.

If you do not submit your renewal report in time to be reviewed at a full Board meeting prior to it expiring, the study will expire and the REB will suspend all study activities until such time as ethical approval can be reinstated.

If you have any questions, please do not hesitate to contact me at extension 15072.

Sincerely,

Amy Geertsma

Manager, REB Administrative Office
Ottawa Health Science Network Research Ethics Board