

## FAILURE TO COMPLY WITH REQUIREMENT FOR ANNUAL RENEWAL

### 1. PURPOSE

This guidance note explains the consequences to the investigator for failing to submit an application for renewal of a previously approved ongoing study.

### 2. REQUIREMENTS FOR ANNUAL RENEWAL

The UBC REB policies/procedures correspond to, and therefore comply with, the pertinent Tri-Council Policy Statement (TCPS2) on 'Ethical Conduct for Research Involving Humans'<sup>1</sup>, specifically Article 6.14 which states, "**At minimum, continuing research ethics review shall consist of an annual status report (for multi-year research projects), and an end-of-study report (projects lasting less than a year)**".

In addition, the ICH Good Clinical Practice Guidelines (ICH GCPs)<sup>2</sup> states in Article 3.1.4 that "**The IRB/IEC should conduct continuing review of each ongoing trial at intervals appropriate to the degree of risk to human participants, but at least once per year**".

The initial REB approval for a research study is for a **one-year term** only, such that the approval expires on the one-year anniversary date of the original approval date. Note the following:

- Subsequent renewals also expire on the one-year anniversary date of the approval for renewal.
- Amendments approved after the initial approval/renewal date, also expire at the same time as the initial approval/renewal of the study.
- Ongoing studies must be renewed on an annual basis after undergoing the appropriate level of REB review.

### 3. PRINCIPAL INVESTIGATOR OBLIGATIONS

The principal investigator/designate for a study must submit an application for renewal to the REB for review and approval on an annual basis until such time as all data collection per the approved protocol is complete, at which time the REB should be notified of the study's completion.

The REB office issues follow up notices to investigators approximately four to five weeks before the expiry date of a study. It is expected that the investigator will respond to this notice either by submitting an application for renewal or for study closure.

Refer to the following link for the Guidance Notes on 'Application for Renewal of a Previously Approved Study' and on 'Notification of Study Closure'.

<http://rise.ubc.ca/guidancenotes.asp>

### 4. FAILURE TO COMPLY WITH REQUIREMENT FOR ANNUAL RENEWAL

Failure to apply for annual renewal before the expiry date of the study's current REB's certificate of approval or to notify the REB office of any reason for delay may result in the following actions being taken:

- The REB may hold the review/approval of current or future submissions by the Principal Investigator or the Department until the status of these studies has been addressed.
- The REB may be required to notify the funding agency/industry sponsor of the expiry of ethics approval for the study
- The REB will *terminate* the ethical approval on the RISE system. Reactivation of the study thereafter will require a new application for ethical review
- After due consultation with the REB Chair and Sr. Administration, the funding for the study will be frozen.

<sup>1</sup> Canada: Tri-Council Policy Statement 2: Ethical Conduct for Research Involving Humans. 2010. Available at <http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/>

<sup>2</sup> Canada: Good Clinical Practice: Consolidated Guideline. ICH Harmonised Tripartite Guideline. 1997. Available at <http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/ich/efficac/e6-eng.php>