

EXPIRED ETHICS CERTIFICATIONS

Ethics certifications are valid for a **one-year** period. The onus is on the Principal Investigator (PI) to ensure studies are renewed in a timely manner. This responsibility is stated in the original certification letter. Effective Dec 11th, 2015, the management of expired ethics certificates is an automated system process via IRISS.

To assist with the renewal process, the system provides automated reminders:

- 1) **30** days before expiry
- 2) **15** days before expiry
- 3) **7** days before expiry

If no action is taken by the PI before the expiry date, the ethics certification will expire, and a system notification is generated. **A closure report can be submitted for up to 29 days after the expiry date.** If a closure report is not submitted within this timeframe, the system will close the ethics certification. Automated closures are a breach of Investigator responsibility.

Where the certification has lapsed, **all research-related activities must be immediately suspended**, except where such suspension puts participants at risk. Expired certificates are non-compliant with the National Research Ethics Standard (TCPS2) and are not consistent with good clinical practice requirements. Expired certifications may require that a new application be submitted; recruitment activities are not permitted until a valid certification is in place.

RENEWAL OF EXPIRED STUDIES

The **Chair** of the REB determines if a renewal request will be permitted when a certificate has expired. A request for Chair Consideration only applies when there are **extenuating circumstances** (*i.e. PI illness or other unforeseen circumstance; PI left organization/clinic and Co-I inherits the study*) which prevent the Principal Investigator from submitting the renewal request before the expiry date. (*PI being busy, on vacation, or no Coordinator on the study are not considered extenuating circumstances*).

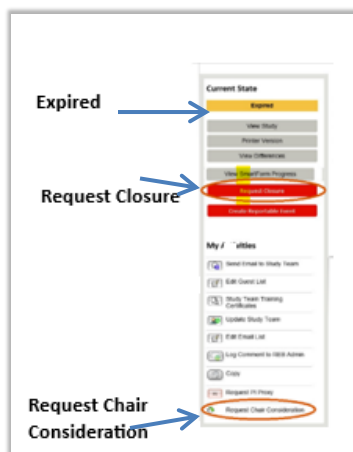
REQUEST FOR CHAIR CONSIDERATION

In such cases, a **“Request for Chair Consideration”** can be submitted within **29 days** of the expiry date via IRISS. The following questions must be addressed for Chair consideration.

- 1) Clarify the reason for the lapse in expiry.
- 2) What preventative measures have you undertaken to ensure the annual renewal is submitted as required (*which is in the 30-day window immediately prior to the expiration date*)?
- 3) What research took place between when the study expired and submission of this request for Chair consideration?

STUDY WORKSPACE

In IRISS; on the left-hand side of the study workspace, click on **Request Closure** or **Request Chair Consideration**.



If requesting Chair Consideration, when you click on the activity, the following pop-up box will open. Provide an answer for the questions and click OK in the bottom right-hand corner of the page.

Request Chair Consideration

A request for Chair consideration only applies when there are **extenuating circumstances** which prevented the Principal Investigator from submitting the renewal request before the expiry date. In such cases, complete the following questions which will be considered by the Chair.

* Clarify the reason for the lapse in expiry:

* What preventative measures have you undertaken to ensure the annual renewal is submitted as required (which is in the 30 day window immediately prior to the expiration date)?

* What research took place between when the study expired and submission of this request for Chair consideration?

Note: This request for Chair consideration does NOT replace completing the renewal request. If granted, the Principal Investigator will have 7 days to submit the renewal request.

Clicking OK will immediately route the request to the Chair.

OK Cancel

When a **Request Chair Consideration** is made, the Chair will determine if the request to submit a renewal is approved or declined. A system notification will be generated when the determination is granted.

If approved, the PI will be able to submit an annual renewal request as they normally would but would need to do so within **7 days** of the Chair's approval or the current state will return to expired.