

EXPIRED ETHICS CERTIFICATIONS

Ethics certifications are valid for up to one year. 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 December 11, 2015 the management of expired ethics certificates is an automated process within IRISS.

Where an ethics certificate 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 ([TCPS 2 2014](#)) and are not consistent with good clinical practice requirements.

The process for studies that have a lapsed ethics certification will be a system-generated study expiry and automated closure. If studies enter into an expired state, PIs will not be able to submit new applications until the expired certifications have either been renewed or closed. Expired certifications that are closed by the system, will require a new application be submitted as the system will not allow reactivations.



To assist with the renewal process, the system provides the PI and study team automated reminders at:

- 1) 30 days prior to expiry
- 2) 15 days prior to expiry
- 3) 7 days prior to expiry

If no action is taken by the PI before the expiry date, the ethics certification will expire. An expired system notification is sent to the PI, Co-Investigators and study team. A closure report can be submitted for **29 days** after the expiry date. If a closure report is not submitted within this time frame, the system will close the ethics certification and a closure notification is sent to the PI, Co-I's and study team. These notifications are also provided, if applicable to the study, to Alberta Health Services (AHS) and/or Covenant Health.

RENEWAL OF EXPIRED STUDIES

The Chair of the REB determines if a renewal request will be permitted when a study has expired. A request for the Chair's consideration applies only when there are **extenuating circumstances** which prevents the PI from submitting the renewal request before the expiry date.

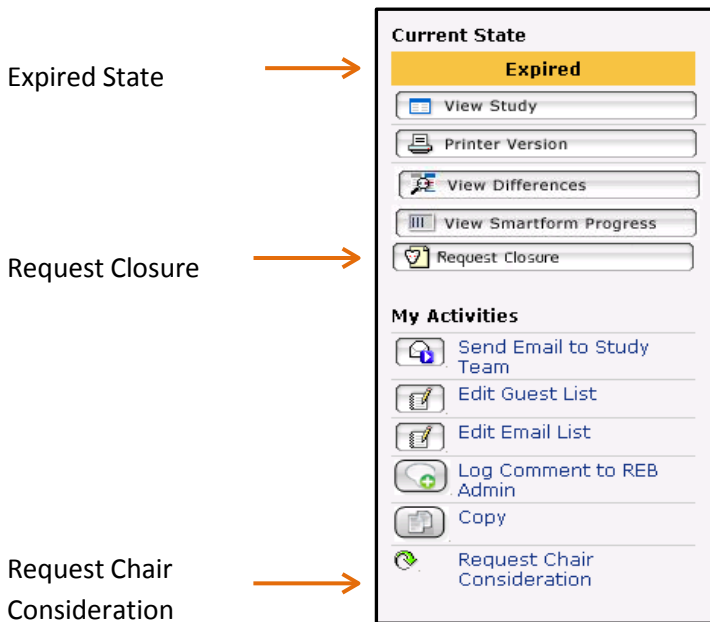
	
<p>Illness or other unforeseen extenuating circumstance PI left research institution; Co-I inherits the study</p>	<p>Busy Out of town; on vacation Coordinator not on study Coordinator does not have IRISS account Don't know how to close or renew study</p>

REQUEST FOR CHAIR CONSIDERATION

In extenuating circumstances, a Request for Chair Consideration can be submitted within **29 days** of the expiry date, if not, the expired certification will be closed by the system. The following must be addressed by the PI for the Chair’s consideration:

1. Clarify the reason for the lapse in expiry.
2. The preventative measures that have been undertaken to ensure that future annual renewals are submitted as required, which is in the 30 day window immediately prior to the expiration date.
3. Whether research took place between when the study expired and submission of this request for Chair consideration.

IRISS WORKSPACE



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 state will return to expired.

QUESTIONS?

General Inquiries: info@hreba.ca

Technical “how to” Inquiries: iriss.support@ucalgary.ca