CREATE A RENEWAL - CHREB

GENERAL GUIDANCE

1. Ethics approval is valid for one year. Regulatory standards (i.e., TCPS2, ICHGCP, 45 CFR 46, 21 CFR 56) and University of Calgary’s Research Integrity Policy mandate that renewals are required on an annual basis to maintain approval.

2. Renewals are reviewed at either the Full Board (above minimal risk) or Delegated board (minimal risk) per TCPS2 standards (Article 6.12).

3. If your renewal requires Full Board review, you are required to submit early enough to ensure it is placed on an agenda prior to the expiry date. The CHREB meets twice a month (on the first and third Thursday of each month).

4. A study can be renewed within 30 days of the expiry date. ‘Create a Renewal’ button appears on study workspace 30 days prior to expiration date.

5. Reminder notifications are sent at 30 days, 15 days, and 7 days before the expiration date.

If you have Modification open during the renewal time period, you will not see ‘Create a Renewal’ button on Study Workspace. In order to complete the Renewal, please withdraw the modification.

6. Submitting a renewal indicates that data collection/interaction with participants is ongoing. If it is submitted by mistake, withdraw the submission or contact your REB administrator (via log comment to REB administrator) for guidance.

FIND THE STUDY YOU WANT TO RENEW

When your study is ready to be renewed, you will be able to see ‘Create a Renewal’ button on your certification workspace. You will also receive reminder notifications from the IRISS System 30 days prior to the expiry date.

1. Log in to IRISS: https://www.ucalgary.ca/iriss/

2. You will find the study under your REB tab. Click on the name of the approved study to open the Study Workspace. (Note: if the study is within 7 days of the expiry date, it is under the INBOX tab)

3. Click on the Create a Renewal activity button found on the left-hand side of the page.
4. This will open the Renewal Request form. Click **Continue** to move to the next page. Moving to the next page will create the Renewal Number. **You must select all categories of research that apply, to access applicable Smart Forms.**

5. Complete the questions on the following pages using the **Continue** button or **Jump To** menu to move through the form.

6. Once you have completed all the questions, click **Save & Close** on the last page to return to the Renewal Workspace.
SUBMIT THE RENEWAL FOR REVIEW

Depending on your role on the study:

1. If you are a member of the study team; you can Create, Edit and View the renewal, but not Submit.
2. If you are the Principal Investigator; you can Create, Edit, View and Submit the renewal. Click on Submit Renewal under My Activities on the left side of the page.

3. The system will conduct an ‘error check’ to identify if any required questions were missed. If any errors are shown, navigate to the indicated questions and fill in the required information. When all the required items are complete, the PI must click Submit Renewal.

4. Read attestations in Submit Renewal box and check box beside “I agree with the above statements:”

5. Click OK to agree and validate your submission.

6. The submission will transition to the next state, Under Ethics Resource Officer Review: Renewal Requested, for review.

7. You will receive an email indicating the submission was successful.