CREATE A RENEWAL - CFREB

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

3. Reminder notifications are sent in IRISS 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.

4. 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.

PREPARING THE RENEWAL REQUEST

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

1. Log in to IRISS: https://research.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.

5. Complete the questions on **General Information** page. An explanation is required based on your response to these questions.

    **General Information**

    1. *Have all modifications been requested and approved?*
       - Yes
       - No
       - N/A
       - Clear
       1.1 If no, briefly describe why modification requests were not submitted:

    2. *Have there been any complaints about the research?*
       - Yes
       - No
       - Clear
       2.1 If yes, briefly describe the complaints:

    3. *Have there been any new or relevant information about the risks associated with the research in the last 12 months?*
       - Yes
       - No
       - Clear
       3.1 If yes, briefly describe this new or relevant information:

    Click the **Save & Close** button to close this form. (This action does not submit the renewal request)

**Important!**

**Q1:** An explanation is required if you answer **“No”** to this question.

**Q2.0 and Q3.0:** An explanation is required if you answered **“Yes”** to either of these questions.

As noted in the TCPS2 Article 6.14, the level of research ethics review may be adjusted over the life of the study based on the level of risk and assessment by Research Ethics and Compliance staff, and at the discretion of the CFREB Board Chair. Thus, an annual renewal submission of a study approved under delegated review at the time of certification may be elevated to the full board if there is an increase in risk to or other ethical implications for the participants since the initial review.

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. Click on Submit Renewal under My Activities on the left side of the page. The Principal Investigator and members listed on the study team can Create, Edit, View and Submit the annual renewal.

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 or the study team member must click Submit Renewal.

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

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

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