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. Reminder notifications are sent in IRISS at 30 days, 15 days, and 7 days before the expiration date.
3. Submitting a renewal indicates that data collection/interaction with participants is ongoing. If it is submitted by mistake, withdraw the renewal or contact your REB administrator (via log comment to REB administrator) for guidance.

Important! The Create a Renewal activity button will show on the Certification Study Workspace 30 days prior to the expiry date.

If you have a Modification Open at the time your Renewal is due to be completed, you will not see the Create a Renewal button on the Certification Study Workspace. In order to complete the Renewal, please withdraw the modification.

PREPARING THE RENEWAL REQUEST

When your study is ready to be renewed, you will receive reminder notifications from the IRISS System 30 days prior to the expiry date.

1. Log in to IRISS: https://iriss.ucalgary.ca.
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 the following page.
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 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.

   **Important!** 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.

   **Submit Renewal - Applicant’s Statement**

   **Note:** A renewal request is not a modification. It is a re-certification of the currently approved protocol.

   By clicking OK and submitting this form, you attest to the following:

   • The information contained in this renewal is accurate.

   • The board will be advised of any revisions to the study arising before or after ethical certification is granted.

   • An annual renewal report will be filed one month from the expiry date of the current ethics approval, and a completed/termination report will be filed immediately upon completion of research activity.

   **Note:** Failure to submit renewal or closure reports in a timely manner will be considered a breach of University of Calgary and Tri-Council policy, and may result in the suspension of research funding. Conduct of research using human subjects that has not received ethics certification is a breach of University policy on integrity in scholarly activity.

   I agree with the above statements:* ☑

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.