

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.

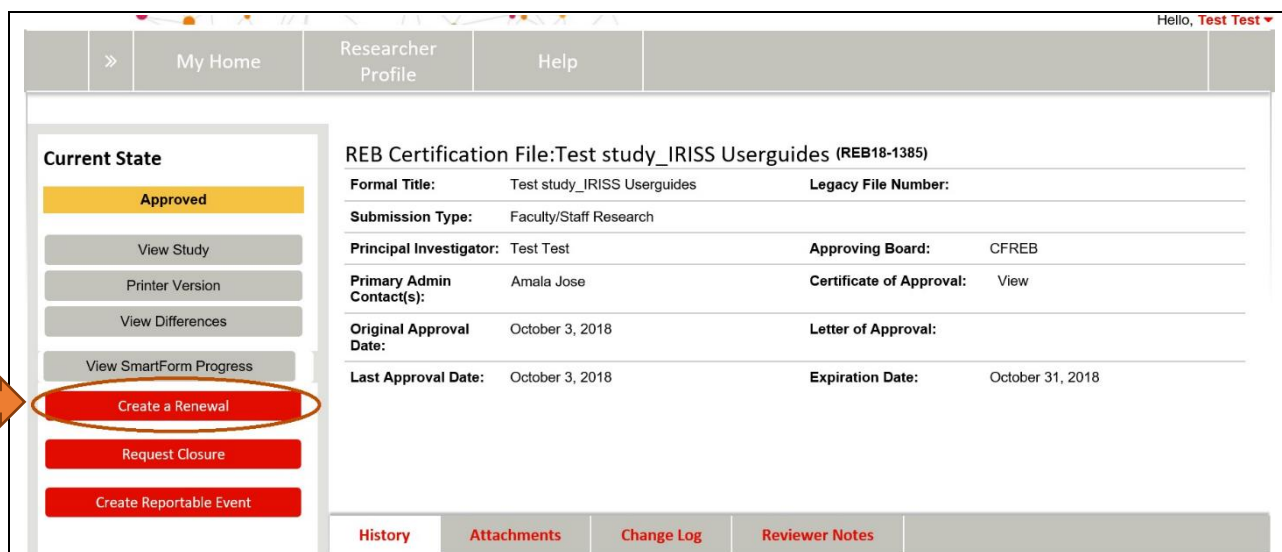
If you have Modification open during the renewal time period, you will not see 'Create a Renewal' button on Study Workspace. In order to complete the Renewal, please withdraw the modification.

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://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.



The screenshot displays the IRISS Study Workspace interface. At the top, there is a navigation bar with 'My Home', 'Researcher Profile', and 'Help' tabs. The main content area is titled 'REB Certification File: Test study_IRISS Userguides (REB18-1385)'. It contains a table of study details:

Formal Title:	Test study_IRISS Userguides	Legacy File Number:	
Submission Type:	Faculty/Staff Research	Approving Board:	CFREB
Principal Investigator:	Test Test	Certificate of Approval:	View
Primary Admin Contact(s):	Amala Jose	Letter of Approval:	
Original Approval Date:	October 3, 2018	Expiration Date:	October 31, 2018
Last Approval Date:	October 3, 2018		

On the left side, under 'Current State', there is a yellow 'Approved' button and several other buttons: 'View Study', 'Printer Version', 'View Differences', 'View SmartForm Progress', 'Create a Renewal' (highlighted with a red oval and an arrow), 'Request Closure', and 'Create Reportable Event'. At the bottom, there are tabs for 'History', 'Attachments', 'Change Log', and 'Reviewer Notes'.

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

General Information

1.0 * Have all modifications been requested and approved?

Yes

No

N/A

[Clear](#)

1.1 If **no**, briefly describe why modification requests were not submitted:

2.0 * Have there been any complaints about the research?

Yes

No

[Clear](#)

2.1 If **yes**, briefly describe the complaints:

3.0 * Has 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.

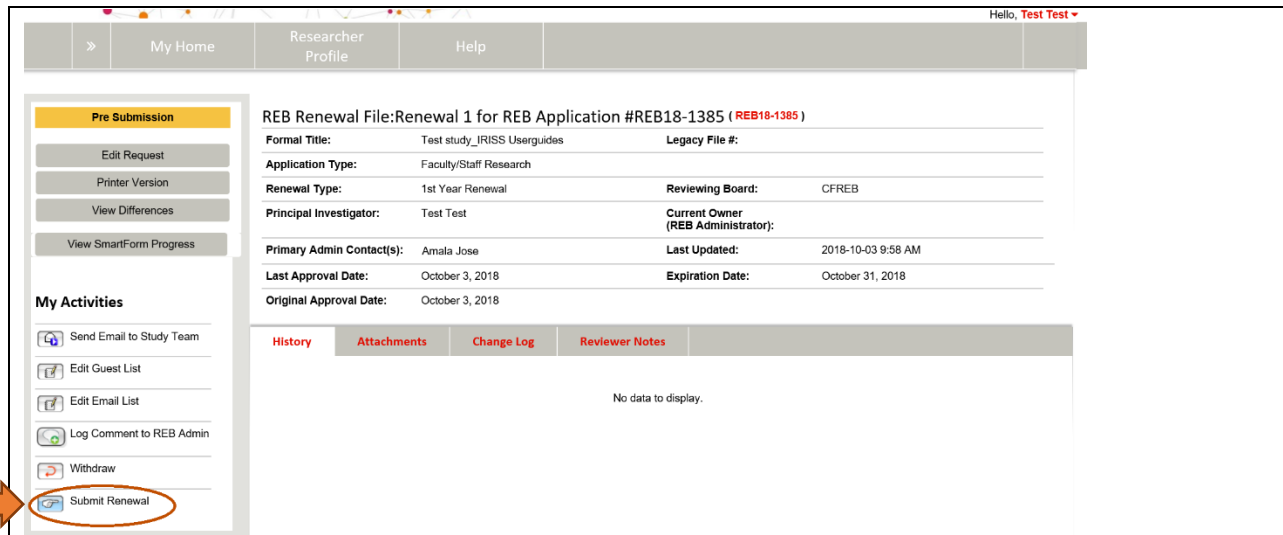
As noted in the TCPS2 Article **6.14**, the level of research ethics review may be adjusted over the life of the study based on the level of risk and assessment by Research Ethics and Compliance staff, and at the discretion of the CFREB Board Chair. Thus, an annual renewal submission of a study approved 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.

- 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.

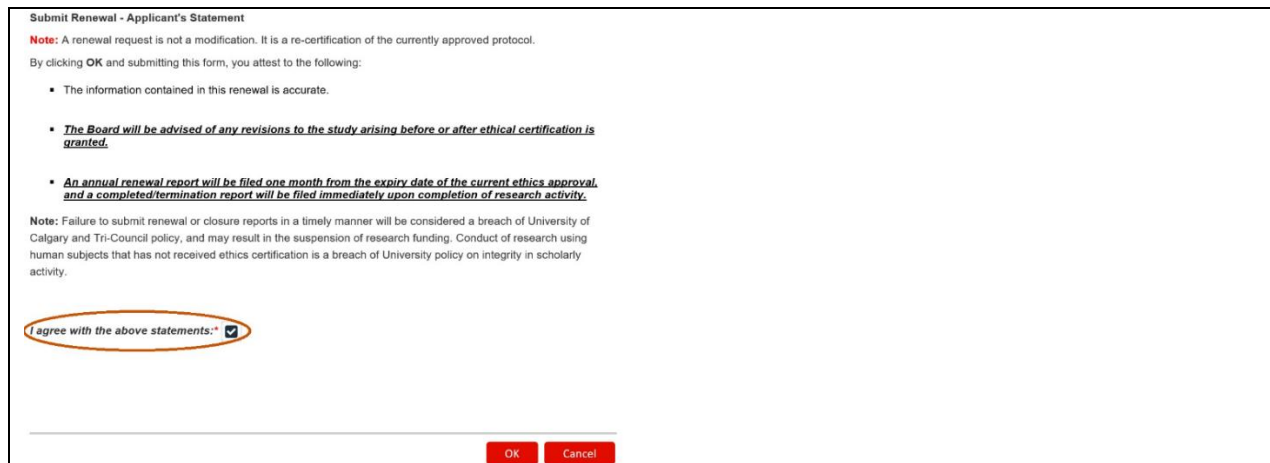


The screenshot shows the IRISS system interface. At the top, there are navigation tabs: 'My Home', 'Researcher Profile', and 'Help'. A user greeting 'Hello, Test Test' is visible in the top right. The main content area displays details for a 'REB Renewal File: Renewal 1 for REB Application #REB18-1385 (REB18-1385)'. The details include:

- Formal Title: Test study_IRISS Usarguides
- Application Type: Faculty/Staff Research
- Renewal Type: 1st Year Renewal
- Principal Investigator: Test Test
- Primary Admin Contact(s): Amala Jose
- Last Approval Date: October 3, 2018
- Original Approval Date: October 3, 2018
- Legacy File #: (blank)
- Reviewing Board: CFREB
- Current Owner (REB Administrator): (blank)
- Last Updated: 2018-10-03 9:58 AM
- Expiration Date: October 31, 2018

 Below the details is a tabbed interface with 'History', 'Attachments', 'Change Log', and 'Reviewer Notes'. The 'History' tab is active, showing 'No data to display.' On the left sidebar, under 'My Activities', the 'Submit Renewal' button is highlighted with an orange circle and an arrow pointing to it.

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:"



The screenshot shows the 'Submit Renewal - Applicant's Statement' form. It includes a note: 'Note: A renewal request is not a modification. It is a re-certification of the currently approved protocol.' Below this, it states: 'By clicking OK and submitting this form, you attest to the following:'. There are three bullet points:

- 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.

 A note at the bottom states: '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.' At the bottom of the form, the checkbox 'I agree with the above statements:' is checked and circled in orange. There are 'OK' and 'Cancel' buttons at the very bottom.

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.