

CREATE A RENEWAL- CHREB

GENERAL GUIDANCE

1. Ethics approval is valid for one year. Regulatory standards (i.e., [TCPS 2: CORE-2022 \(tcps2core.ca\)](https://tcps2core.ca), 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://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.



Current State

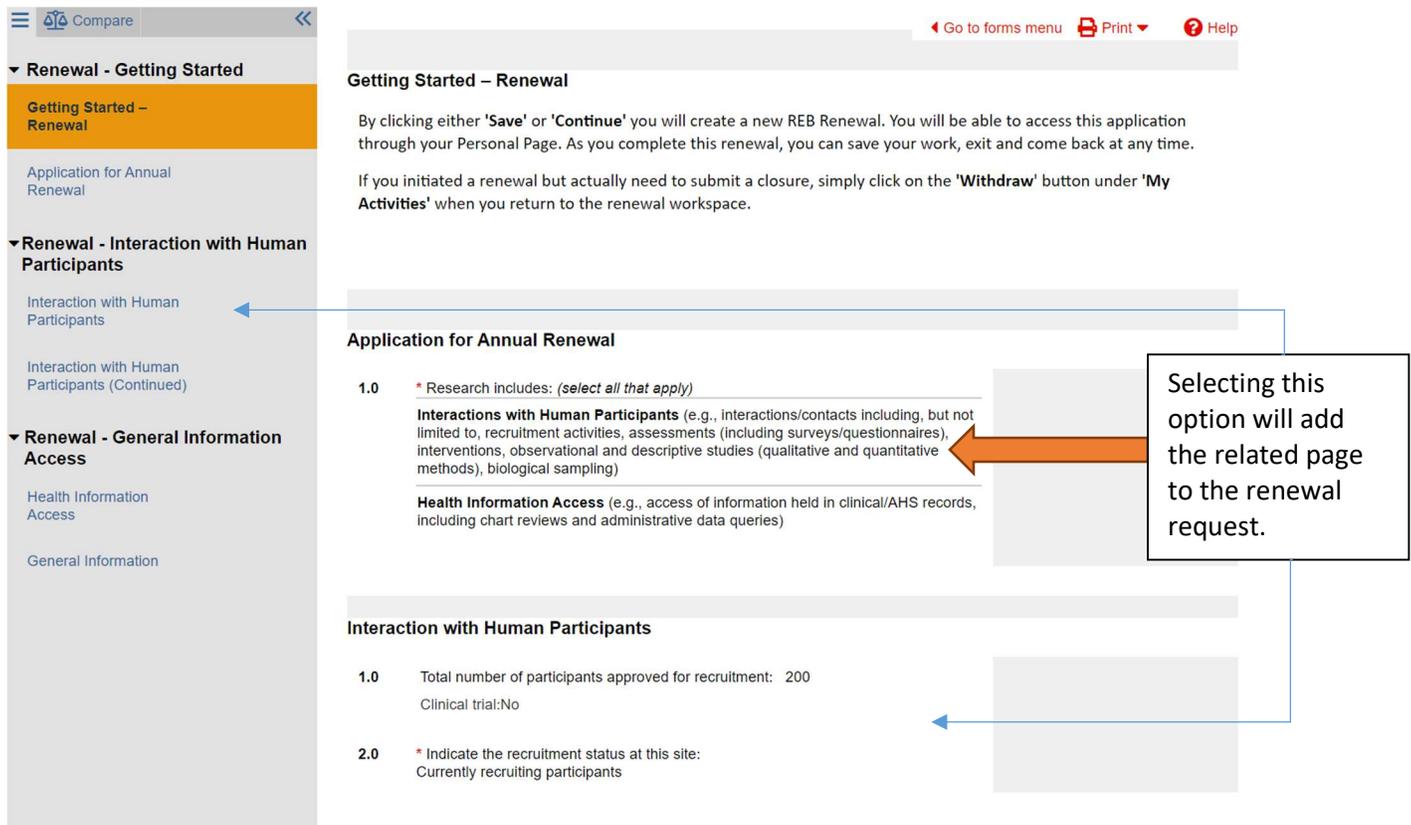
- Approved
- View Study
- Printer Version
- View Differences
- View SmartForm Progress
- Create a Renewal**
- Request Closure
- Create Reportable Event

REB Certification File: Test Study2 (REB18-1384)

Formal Title:	Test study title - long title placeholder	Legacy File Number:	
Submission Type:	Faculty/Staff Research		
Principal Investigator:	Test Test	Approving Board:	CHREB
Primary Admin Contact(s):	Amala Jose Test Test	Certificate of Approval:	View
Original Approval Date:	October 1, 2018	Letter of Approval:	
Last Approval Date:	October 1, 2018	Expiration Date:	October 31, 2018

History Attachments Change Log Reviewer Notes

4. This will open the Renewal Request form. Moving to the next page will create the Renewal Number. **You must select all categories of research that apply, to access applicable Smart Forms.**



Getting Started – Renewal

By clicking either 'Save' or 'Continue' you will create a new REB Renewal. You will be able to access this application through your Personal Page. As you complete this renewal, you can save your work, exit and come back at any time.

If you initiated a renewal but actually need to submit a closure, simply click on the 'Withdraw' button under 'My Activities' when you return to the renewal workspace.

Application for Annual Renewal

1.0 * Research includes: (select all that apply)

Interactions with Human Participants (e.g., interactions/contacts including, but not limited to, recruitment activities, assessments (including surveys/questionnaires), interventions, observational and descriptive studies (qualitative and quantitative methods), biological sampling)

Health Information Access (e.g., access of information held in clinical/AHS records, including chart reviews and administrative data queries)

Interaction with Human Participants

1.0 Total number of participants approved for recruitment: 200
Clinical trial: No

2.0 * Indicate the recruitment status at this site:
Currently recruiting participants

Selecting this option will add the related page to the renewal request.

5. Complete the questions on the following pages using the **Continue** button or the left-hand navigation page menu to move through the form.
6. Once you have completed all the questions, click **Finish** on the last page to return to the Renewal Workspace.
7. Click on **Exit** or **Finish (This action does NOT submit the renewal request)**

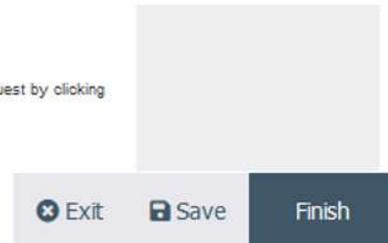
General Information

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

You will be directed to the Renewal Workspace.

Once all required information has been entered, the Principal Investigator will be able to submit the renewal request by clicking on the 'Submit Renewal' activity button on the left-side menu of the Renewal Workspace.

Click REB18-1101 to view the current approved Study.



SUBMIT THE RENEWAL FOR REVIEW

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.

2. 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**.
3. Read attestations in Submit Renewal box and **check box** beside **"I agree with the above statements:"**

4. 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:

OK

Cancel

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.
8. Please contact the IRISS Help Desk if you would like additional support: iriss.support@ucalgary.ca (403) 210-9300 or 1-855-222-2345.