

Important! The Create a Renewal button will show on the Certification Study Workspace <u>30 days</u> 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, either withdraw the modification (if in the state: PreSubmission) or wait until the Modification has been approved.

FINDING THE STUDY YOU WANT TO RENEW

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: <u>https://iriss.ucalgary.ca/IRISSPROD/login/</u>
- 2. You will find the study under your REB Tab. Click on the name of the approved study to open the Study Workspace.
- 3. Click on the Create a Renewal activity button found on the left hand side of the page.

| Approved | | | | |
|----------|--------------------|--|--|--|
| Viev | Study | | | |
| 😑 Prin | ter Version | | | |
| E View | w Differences | | | |
| III Viev | Smartform Progress | | | |
| 2 Crea | te a Renewal | | | |
| 7 Requi | est Closure | | | |

- 4. This will open the Renewal Request form. Click Continue to move to the next page.
- 5. Moving to the next page will create the Renewal Number:

| < Back | ere: 🕐 Modification Testing 2 - Instr 🥳 👘 🗤 🗆 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 | Hide/Show Errors Print Jump To: Renewal Questions (Contin | und) - | Continue > | | |
|--------|---|---|--------------------|--|--|--|
| | 1 Space Level | Lundonou criora Luncost anile Los reneran dendera Concer | and - | | | |
| enev | val Questions | | | | | |
| | If this renewal request is for a clinical trial, indicate the recruitment status: | | | | | |
| | O Currently recruiting participants | | | | | |
| | Recruitment complete (check all that apply) | | | | | |
| | Clear | | | | | |
| | Participants receiving study treatment | | | | | |
| | Participants undergoing protocol mandated interventions that are not part of standard care | | | | | |
| | Post-intervention follow-up and data collection only | | | | | |
| | Intervention and follow-up complete – analysis, data clarification, data transfer ongoing | | | | | |
| | 1.1 Date recruitment completed: | | | | | |
| | Provide the following information: 2.1 Total number of participants approved to recruit: | | | | | |
| | | | | | | |
| | 2.1 Total number of participants approved to recruit: | Lead Site | Participating Site | | | |
| 0 | 2.1 Total number of participants approved to recruit: | Lead Site | Participating Site | Note: Enter '0' if there are no participants in the category | | |
| 0 | 2.1 Total number of participants approved to recruit: 2.2 Number of participants recruited in the last 12 months: If this renewal request is for a clinical trial, provide the following information: | Lead Site | Participating Site | participants in the category | | |
| o | 2.1 Total number of participants approved to recruit: 2.2 Number of participants recruited in the last 12 months: 3.1 Total number of participants consented locally | Lead Site | Participating Site | participants in the category Note: Provide information onl for the 12 months immediated prior to current anniversary | | |
| .0 | 2.1 Total number of participants approved to recruit: 2.2 Number of participants recruited in the last 12 months: 3.1 Number of participants provide the following information: 3.1 Number of participants consented locally 3.2 Number of participants consented locally but did not meet inclusion criteria | Lead Site | Participating Site | participants in the category Note: Provide information only for the 12 months immediately prior to current anniversary date and do not aggregate data since the start of the | | |
| 0 | 2.1 Total number of participants approved to recruit: 2.2 Number of participants recruited in the last 12 months: 1f this renewal request is for a clinical trial, provide the following information: 3.1 Number of participants conserted locally 3.2 Number of participants conserted locally but did not meet inclusion oriteria 3.3 Number of participants withdrawn from the study | Lead Sile | Participating Site | Note: Provide information one for the 12 months immediated prior to current anniversary date and do not apprepate data since the start of the study unless specifically requested by the ERO for you | | |
| o | 2.1 Total number of participants approved to recruit: 2.2 Number of participants recruited in the last 12 months: 2.1 Total number of participants conserted locally 3.1 Number of participants conserted locally but did not meet inclusion criteria 3.2 Number of participants conserted locally but did not meet inclusion criteria 3.4 Number of participants withdrawn from the study | Lead Site | Participating Site | participants in the category Note: Provide information of the for the 12 months immediatel prior to current anniversary date and do not aggregate data since the start of the study unless specifically | | |
| 2 | 2.1 Total number of participants approved to recruit: 2.2 Number of participants recruited in the last 12 months: 2.1 Total number of participants conserted locally 3.1 Number of participants conserted locally but did not meet inclusion criteria 3.2 Number of participants conserted locally but did not meet inclusion criteria 3.4 Number of participants withdrawn from the study | Lead Site | Perticipating Site | participants in the category Note: Provide informations on or for the 21 months immediatell prior to current anniversary date and do not appreate study unless specifically requested by the ERO for you | | |
| 3 | 2.1 Total number of participants approved to result: 2.2 Number of participants excluded in the last 12 months: 2.3 Number of participants conserted locally 3.1 Pumber of participants conserted locally but did not meet inclusion oriteria 3.2 Number of participants conserted locally but did not meet inclusion oriteria 3.3 Number of participants which are not the study 3.4 Number of participants in follow-up 3.5 Number of participants which have completed follow-up * Have all protocol violations or deviations been reported? | Lead Site | Participating Site | participants in the category Note: Provide information on for the 21 months immediatel prior to current anniversary date and do not appreciate study unless specificatly reguested by the ERD for you | | |
| .0 | 2.1 Total number of participants approved to recruit: 2.2 Number of participants recruited in the last 12 months: 11 this renewal request is for a clinical trial, provide the following information: 3.1 Number of participants conserted locally but dd not meet inclusion orteria 3.2 Number of participants in follow up 3.4 Number of participants in follow up 3.5 Number of participants in holiow up 3.5 Number of participants who have completed follow up * Nave all protocol violations or deviations been reported? Yes | Lead Site | Participating Site | participants in the category Note: Provide information on for the 21 months immediatel prior to current anniversary date and do not appreciate study unless specificatly reguested by the ERD for you | | |

General inquiries: <u>info@hreba@ucalgary.ca</u> Technical 'how to': <u>iriss.support@ucalgary.ca</u>



Important!

Questions 1.0 and 3.0 only need to be completed if your study is a clinical trial.

Question 2.0 – for studies that are not a clinical trial, the term 'participants; should be interpreted as charts and/or biological samples accessed, as appropriate.

- 6. Complete the questions on the following pages using the Continue button or Jump To menu to move through the form.
- 7. Once you have completed all the questions, click Save & Close on the final page to return to the Study Workspace.

SUBMITTING 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 Application 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 for review.
- 7. You will receive an email indicating the submission was successful.

SUBMITTING OTHER ITEMS

After the renewal has been submitted, the ability to submit other items associated with that renewal depends on your role on the study.

| | | FEATURES | | | | |
|-------|------------------------------|---|-------------------|----------------------|---|--|
| | ACCESS BREAKDOWN | Start Renewal | Submit Renewal | Writing / Editing | Submit Changes | |
| ROLES | Principal Investigator | < | > | > | Image: A set of the set of the | |
| | Co-Investigator | < | X | ~ | X | |
| | Co-Investigator (Student) | < | X | > | X | |
| | Primary Admin Contact* | Image: A start of the start of | X | ~ | X | |

*Research Assistant (anyone added in Question 6 on page 2 of the application)