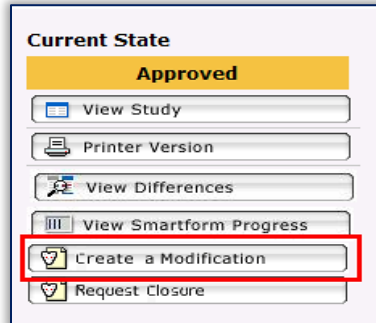


FINDING THE STUDY YOU WANT TO MODIFY

Any modifications/amendments you want to make to your approved is now completed in IRISS:

1. Log in to IRISS: <https://iriss.ucalgary.ca/IRISSPROD/login/>
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 Modification activity button found on the left hand side of the page.



4. This will open the Modification Summary form. Click Continue to move to the next page.

5. This will create the Modification Number:

Edit: REB Modification - HREBA.CC-14-0332_MOD1

Important! You can complete one or more modifications on the same Modification Summary form.

6. On the Full Modification Details page, choose the type of modification you wish to make by placing a checkmark in the appropriate box(s).

Full Modification Details

All questions preceded by a red asterisk () are required responses that map you to the application sections that are relevant to your study. All questions within must be addressed.*

1.0 * Select all applicable changes for this modification:

- Editorial
- Investigative Team e.g., PI, Co-Investigator
- Funding/Budget
- Study Protocol e.g., change to methods, procedures, materials, duration, participant monitoring, treatment dosage, safety
- Investigator Brochure
- Product Monograph
- Participants
- Recruitment e.g., will participants be sought from other sites, agencies or recruited by additional means?
- Consent/Assent Forms
- Reimbursements/Incentives
- Data Monitoring
- Other:

7. Complete all the remaining questions and use the Continue button or Jump To menu to move to the next page. On the Documentation Revision page indicate which documents you are adding or revising.

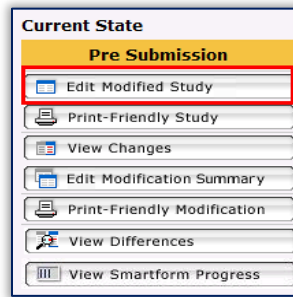
Important! You will add the documents to the Documentation Section on the study when you click on Edit Modified Study (see steps below).

- Once you have completed all the questions, click Save & Close on the final page of the summary form to return to the Study Workspace.

EDIT MODIFIED STUDY

Now you will make changes to the approved study:

- Click on Edit Modified Study on the left hand side of the page.



- This will open a copy of the current approved study where you can use the Jump To menu to navigate to the page(s) you wish to change or to the Documentation page to add/update documents.

Important! Question 1.0 on the Study Identification page remains as New Application – do not change.

- Once you have made all the appropriate changes and added any new/updated documents, click on Save and then Exit to return to the Modification Study Workspace.

Save | Exit | Hide/Show Errors | Print... | Jump To: - Research Ethics Board -

SUBMITTING MODIFICATION FOR REVIEW

Depending on your role on the study:

- If you are a member of the study team; you can create, edit and view the Modification, but not submit.
- If you are the Principal Investigator; you can create, edit, view and submit the Modification. Click on **Submit Modification** under My Activities on the left side of the page.
- 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 Modification**.

- Click **OK** to agree and validate your submission.
- The submission will transition to the next state for review.
- You will receive an email indicating the submission was successful.

SUBMITTING OTHER ITEMS

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

ACCESS BREAKDOWN		FEATURES			
		<i>Start Modification</i>	<i>Submit Modification</i>	<i>Writing / Editing</i>	<i>Submit Changes</i>
ROLES	Principal Investigator	✓	✓	✓	✓
	Co-Investigator	✓	X	✓	X
	Co-Investigator (Student)	✓	X	✓	X
	Primary Admin Contact*	✓	X	✓	X

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