

## MODIFICATION

To modify a study in IRISS, involves three steps:

### I - COMPLETE THE MODIFICATION SUMMARY

- Choose the type of modification
- Provide Summary of changes and answer the remaining questions
- Provide list of uploaded documents as part of modification

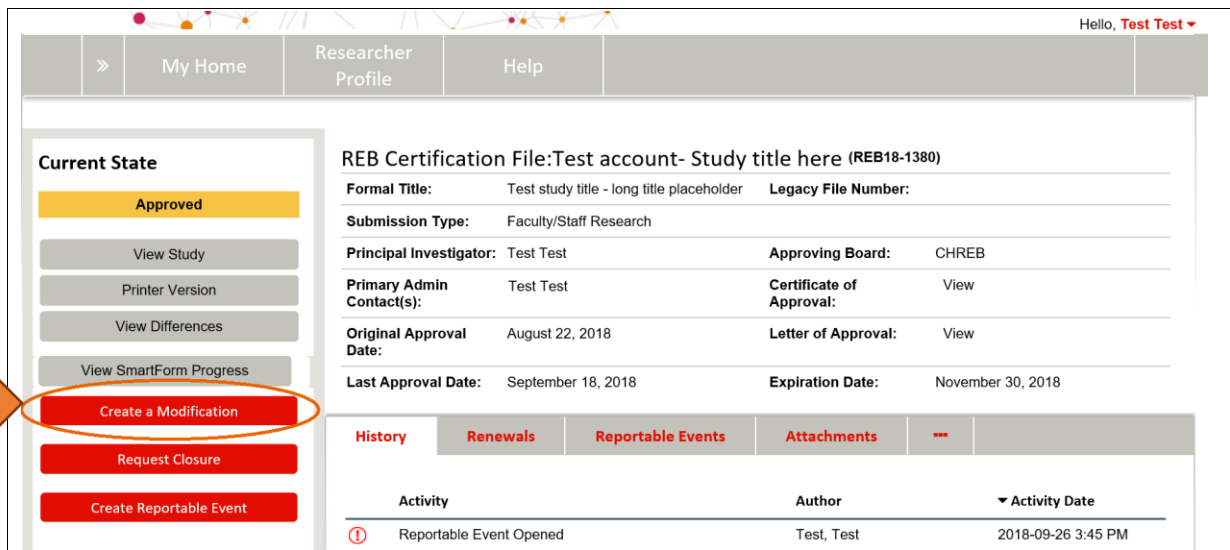
### II - MODIFY THE STUDY

- Click on **Edit modified Study** on Study Workspace
- Make Changes to corresponding pages of application
- Save the changes

### III- SUBMIT THE MODIFICATION

## I. HOW TO COMPLETE THE MODIFICATION SUMMARY

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.
3. Click on the **Create a Modification** 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 Modification**
- Request Closure
- Create Reportable Event

REB Certification File: Test account- Study title here (REB18-1380)

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):	Test Test	Certificate of Approval:	View
Original Approval Date:	August 22, 2018	Letter of Approval:	View
Last Approval Date:	September 18, 2018	Expiration Date:	November 30, 2018

History   Renewals   Reportable Events   Attachments   ...

Activity	Author	Activity Date
Reportable Event Opened	Test, Test	2018-09-26 3:45 PM

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

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

5. 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 the section 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
- Other:

6. Provide a brief description of changes that you are making to the study under Q.2.

2.0 \* Summarize the changes you are making to the approved study:

Provide a brief description of changes that you are making to the study.

7. Complete all the remaining questions and use the **Continue** button or **Jump To** menu to move to the next page.

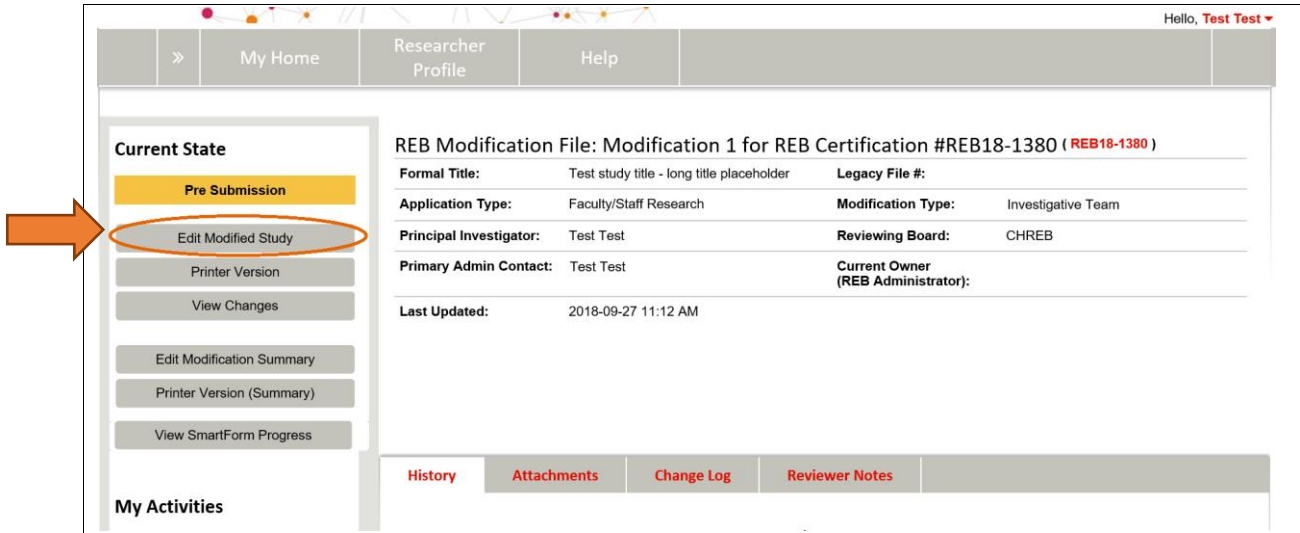
8. On the **Documentation Revision** page, provide the list of documents that you are adding or revising as part of the modification.

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

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

## II. HOW TO MODIFY THE STUDY

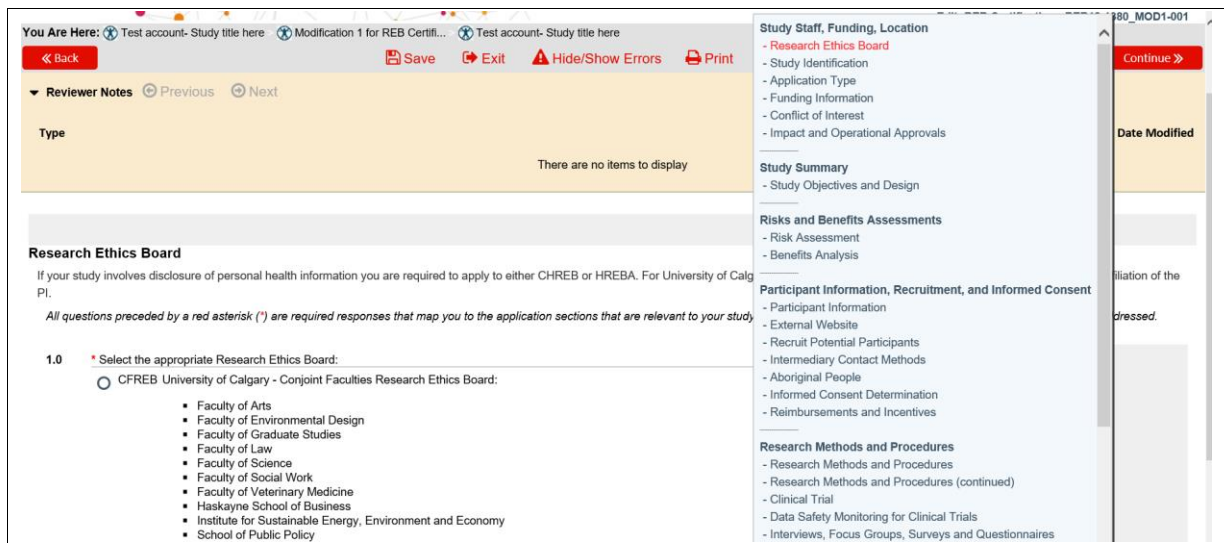
1. Click on **Edit Modified Study** on the left hand side of the page.



The screenshot shows the IRISS system interface. At the top, there are navigation tabs: 'My Home', 'Researcher Profile', and 'Help'. The user is logged in as 'Hello, Test Test'. The main content area is titled 'REB Modification File: Modification 1 for REB Certification #REB18-1380 (REB18-1380)'. Below this, there are several fields: 'Formal Title: Test study title - long title placeholder', 'Legacy File #:', 'Application Type: Faculty/Staff Research', 'Modification Type: Investigative Team', 'Principal Investigator: Test Test', 'Reviewing Board: CHREB', 'Primary Admin Contact: Test Test', and 'Current Owner (REB Administrator):'. A 'Last Updated' timestamp of '2018-09-27 11:12 AM' is also visible. On the left side, under 'Current State', there is a 'Pre Submission' group containing buttons for 'Edit Modified Study', 'Printer Version', and 'View Changes'. An orange arrow points to the 'Edit Modified Study' button. Below this group are buttons for 'Edit Modification Summary', 'Printer Version (Summary)', and 'View SmartForm Progress'. At the bottom, there are tabs for 'History', 'Attachments', 'Change Log', and 'Reviewer Notes'.

2. 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!** Both clean and tracked change copies of all revised documents are required for review.



The screenshot shows the IRISS system interface for a 'Reviewer Notes' page. The top navigation bar includes 'Back', 'Save', 'Exit', 'Hide/Show Errors', and 'Print'. The 'Reviewer Notes' section is currently empty, displaying 'There are no items to display'. Below this, the 'Research Ethics Board' section is visible, containing a question: '1.0 \* Select the appropriate Research Ethics Board:'. The options are: 'CFREB University of Calgary - Conjoint Faculties Research Ethics Board' (selected), 'Faculty of Arts', 'Faculty of Environmental Design', 'Faculty of Graduate Studies', 'Faculty of Law', 'Faculty of Science', 'Faculty of Social Work', 'Faculty of Veterinary Medicine', 'Haskayne School of Business', 'Institute for Sustainable Energy, Environment and Economy', and 'School of Public Policy'. On the right side, there is a 'Jump To' menu with a 'Continue' button and a 'Date Modified' column.

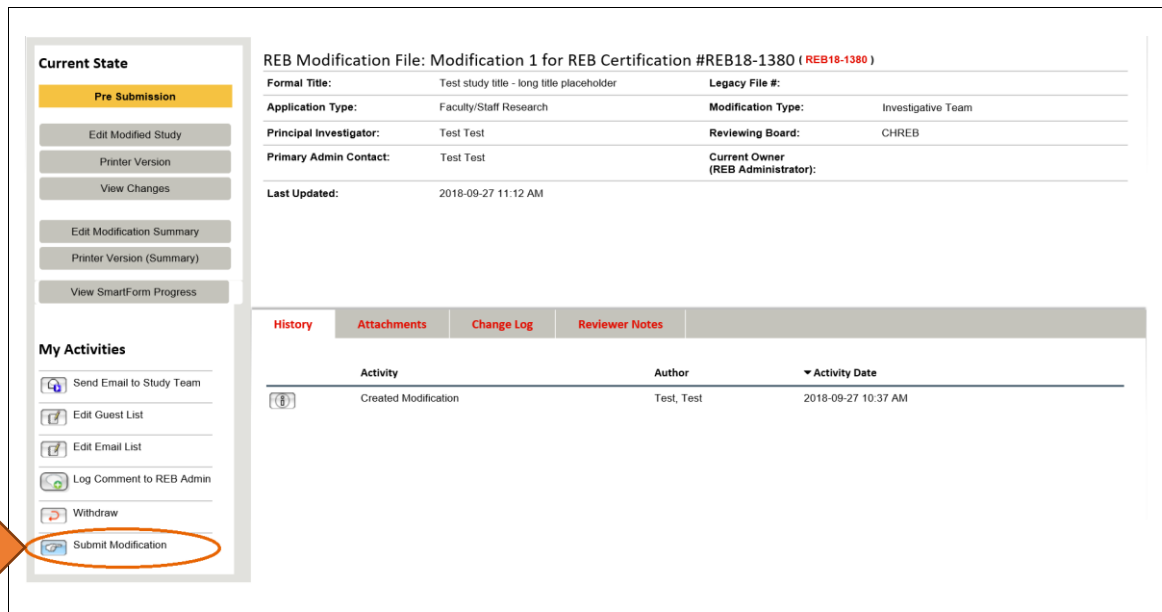
3. Once you have made all the appropriate changes and added any new/updated documents, click on **Save and Close** to return to the Modification Study Workspace.

**Important!** Do not delete the previous version of the document, it will remain in the Document History.

### III. SUBMIT THE MODIFICATION 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 Modification, but not submit.
2. 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.
3. The system will conduct an ‘error check’ to identify if any required questions were missed.



REB Modification File: Modification 1 for REB Certification #REB18-1380 ( **REB18-1380** )

<b>Formal Title:</b>	Test study title - long title placeholder	<b>Legacy File #:</b>	
<b>Application Type:</b>	Faculty/Staff Research	<b>Modification Type:</b>	Investigative Team
<b>Principal Investigator:</b>	Test Test	<b>Reviewing Board:</b>	CHREB
<b>Primary Admin Contact:</b>	Test Test	<b>Current Owner (REB Administrator):</b>	
<b>Last Updated:</b>	2018-09-27 11:12 AM		

**Current State**

- Pre Submission
- Edit Modified Study
- Printer Version
- View Changes
- Edit Modification Summary
- Printer Version (Summary)
- View SmartForm Progress

**My Activities**

- Send Email to Study Team
- Edit Guest List
- Edit Email List
- Log Comment to REB Admin
- Withdraw
- Submit Modification**

**History** | Attachments | Change Log | Reviewer Notes

Activity	Author	Activity Date
Created Modification	Test, Test	2018-09-27 10:37 AM

**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**.

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