

## MODIFY YOUR STUDY

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

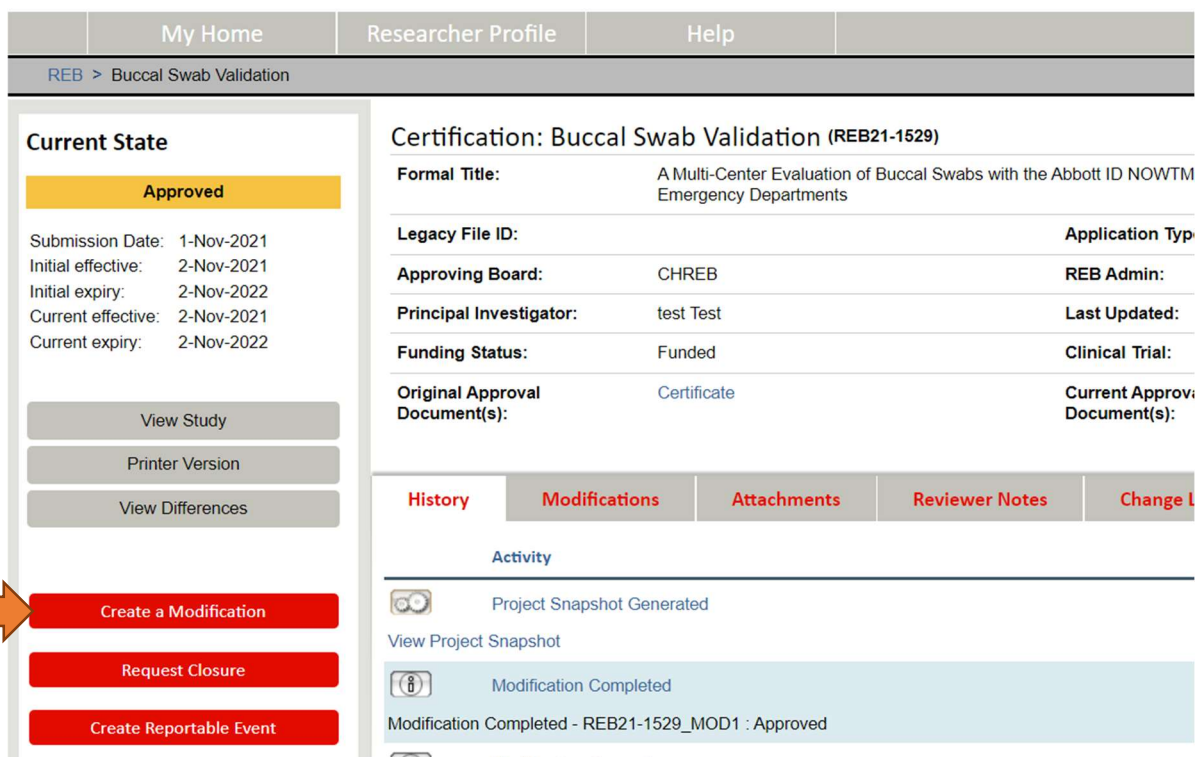
### II - MODIFY THE STUDY

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

### III- SUBMIT THE MODIFICATION

## I. HOW TO COMPLETE THE MODIFICATION SUMMARY

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.
3. Click on the **Create a Modification** found on the left-hand side of the page.



The screenshot displays the IRISS interface for a study titled "Buccal Swab Validation". The top navigation bar includes "My Home", "Researcher Profile", and "Help". Below this, a breadcrumb trail shows "REB > Buccal Swab Validation".

**Current State**

**Approved**

Submission Date: 1-Nov-2021  
Initial effective: 2-Nov-2021  
Initial expiry: 2-Nov-2022  
Current effective: 2-Nov-2021  
Current expiry: 2-Nov-2022

Buttons: View Study, Printer Version, View Differences

**Certification: Buccal Swab Validation (REB21-1529)**

<b>Formal Title:</b>	A Multi-Center Evaluation of Buccal Swabs with the Abbott ID NOWTM Emergency Departments		
<b>Legacy File ID:</b>		<b>Application Type:</b>	
<b>Approving Board:</b>	CHREB	<b>REB Admin:</b>	
<b>Principal Investigator:</b>	test Test	<b>Last Updated:</b>	
<b>Funding Status:</b>	Funded	<b>Clinical Trial:</b>	
<b>Original Approval Document(s):</b>	Certificate	<b>Current Approval Document(s):</b>	

Navigation tabs: History, **Modifications**, Attachments, Reviewer Notes, Change Log

**Activity**

- Project Snapshot Generated
- View Project Snapshot
- Modification Completed
- Modification Completed - REB21-1529\_MOD1 : Approved

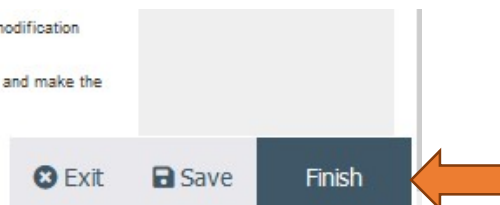
**Left Sidebar (Action Buttons):**

- Create a Modification** (highlighted with an orange arrow)
- Request Closure
- Create Reportable Event

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

Click the 'Save & Close' button to save and exit this form. You will be directed to the Workspace for this modification request.

In order to complete this modification request you need to select the 'Edit Modified Study' activity button and make the changes to your current study.

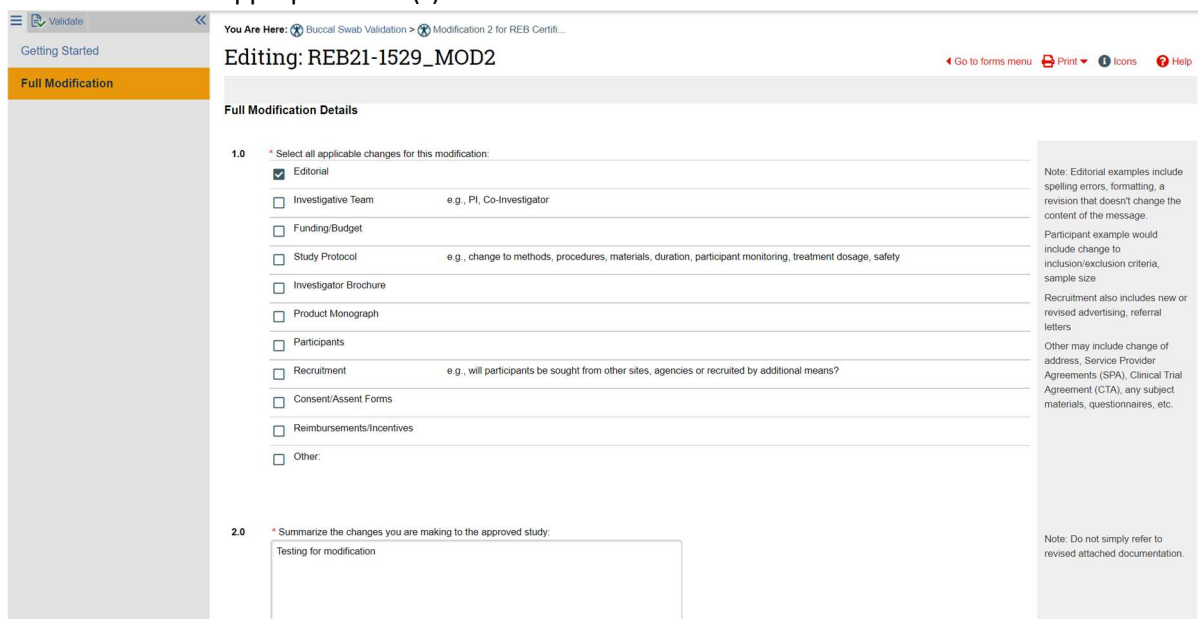


Click the 'Exit or Finish' button to save and exit this form. You will be directed to the workspace for this modification request.

In order to complete this modification request, you need to select the 'Edit Modified Study' activity button and make the changes to your current study.

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

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



**Full Modification Details**

**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:

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

Testing for modification

Note: Editorial examples include spelling errors, formatting, a revision that doesn't change the content of the message.

Participant example would include change to inclusion/exclusion criteria, sample size

Recruitment also includes new or revised advertising, referral letters

Other may include change of address, Service Provider Agreements (SPA), Clinical Trial Agreement (CTA), any subject materials, questionnaires, etc.

Note: Do not simply refer to revised attached documentation.

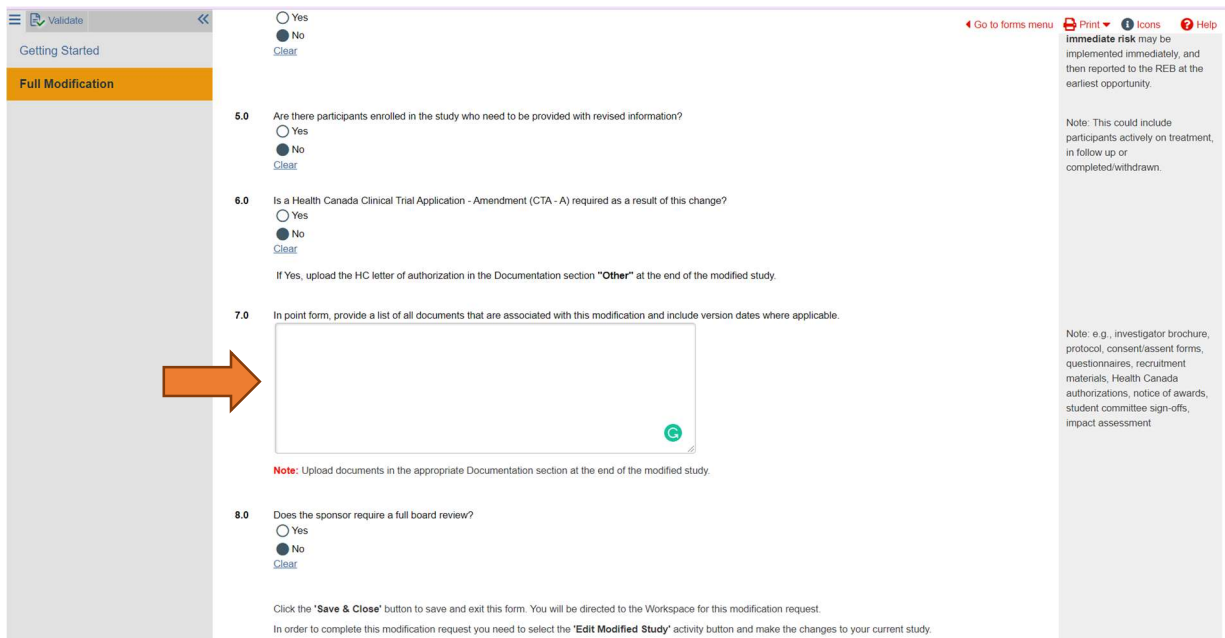
5. Provide a brief description of changes that you are making to the study under Q.2.

2.0

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

7. Complete all the remaining questions and use navigation page on the left hand side of the screen to move to the next page, or click the **Continue** button at the bottom.

8. Under Q.7, provide the list of documents that you are adding or revising as part of the modification.



The screenshot shows a web form titled 'Validata' with a navigation menu on the left. The menu has 'Getting Started' and 'Full Modification' (highlighted in orange). The form contains the following questions:

- 5.0** Are there participants enrolled in the study who need to be provided with revised information?  
☐ Yes  
☒ No  
[Clear](#)
- 6.0** Is a Health Canada Clinical Trial Application - Amendment (CTA - A) required as a result of this change?  
☐ Yes  
☒ No  
[Clear](#)  
 If Yes, upload the HC letter of authorization in the Documentation section "Other" at the end of the modified study.
- 7.0** In point form, provide a list of all documents that are associated with this modification and include version dates where applicable.  

Note: Upload documents in the appropriate Documentation section at the end of the modified study.
- 8.0** Does the sponsor require a full board review?  
☐ Yes  
☒ No  
[Clear](#)

At the bottom, it says: Click the "Save & Close" button to save and exit this form. You will be directed to the Workspace for this modification request. In order to complete this modification request you need to select the "Edit Modified Study" activity button and make the changes to your current study.

On the right side, there is a sidebar with links: Go to forms menu, Print, Icons, Help. Below these links, there are two notes:

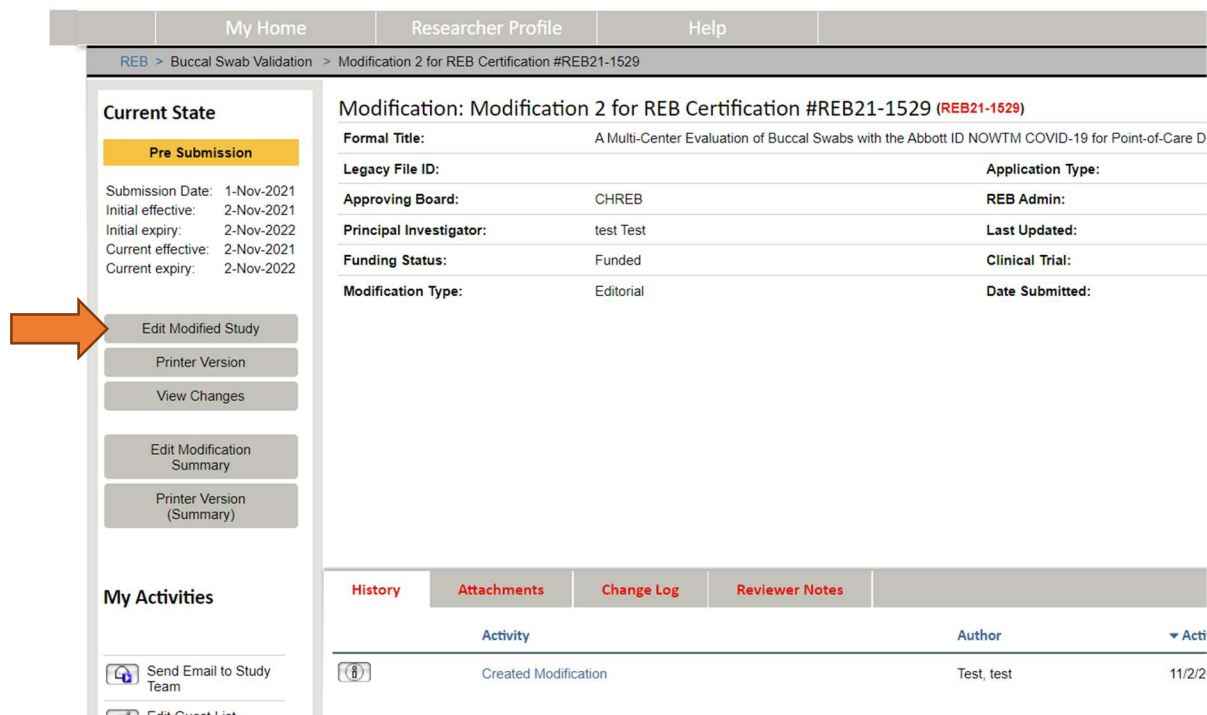
- Immediate risk** may be implemented immediately, and then reported to the REB at the earliest opportunity.  
 Note: This could include participants actively on treatment, in follow up or completed/withdrawn.
- Note: e.g., investigator brochure, protocol, consent/assent forms, questionnaires, recruitment materials, Health Canada authorizations, notice of awards, student committee sign-offs, impact assessment

6. Once you have completed all the questions, click **Save & Finish** on the final page of the summary form to return to the Study Workspace.
7. Click the 'Exit or Finish' button to close this form, this action does NOT submit the application.
8. You will be directed to the certification's 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 interface. At the top, there are navigation tabs: My Home, Researcher Profile, and Help. Below these, a breadcrumb trail reads: REB > Buccal Swab Validation > Modification 2 for REB Certification #REB21-1529.

**Current State**

**Pre Submission**

Submission Date: 1-Nov-2021  
Initial effective: 2-Nov-2021  
Initial expiry: 2-Nov-2022  
Current effective: 2-Nov-2021  
Current expiry: 2-Nov-2022

**Buttons:** Edit Modified Study (highlighted with an orange arrow), Printer Version, View Changes, Edit Modification Summary, Printer Version (Summary).

**My Activities**

Send Email to Study Team, Edit Queue List

**Modification: Modification 2 for REB Certification #REB21-1529 (REB21-1529)**

**Formal Title:** A Multi-Center Evaluation of Buccal Swabs with the Abbott ID NOWTM COVID-19 for Point-of-Care D

**Legacy File ID:** **Application Type:**

**Approving Board:** CHREB **REB Admin:**

**Principal Investigator:** test Test **Last Updated:**

**Funding Status:** Funded **Clinical Trial:**

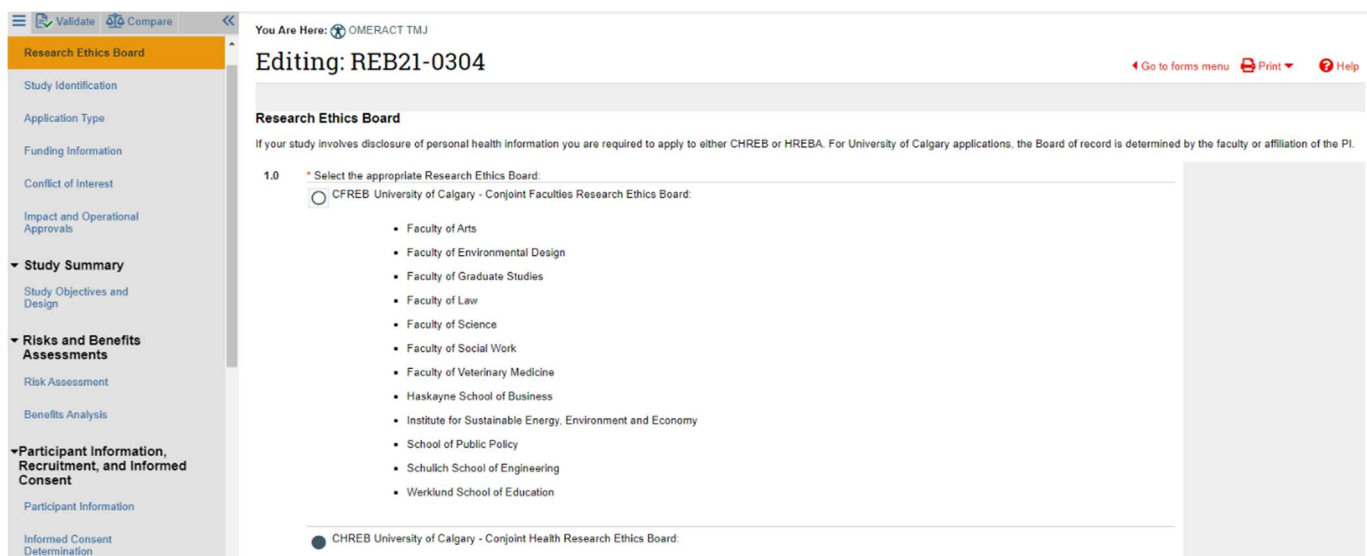
**Modification Type:** Editorial **Date Submitted:**

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

Activity	Author	Acti
Created Modification	Test, test	11/2/2

2. This will open a copy of the current approved study where you can use the **Continue** button, or the navigation pane on the left-hand side 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 'Editing: REB21-0304' form. At the top, there are navigation tabs: Validate, Compare, and Help. Below these, a breadcrumb trail reads: You Are Here: OMERACT TMJ.

**Research Ethics Board**

If your study involves disclosure of personal health information you are required to apply to either CHREB or HREBA. For University of Calgary applications, the Board of record is determined by the faculty or affiliation of the PI.

1.0 \* Select the appropriate Research Ethics Board:

☐ CFREB University of Calgary - Conjoint Faculties Research Ethics Board:

- 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
- School of Public Policy
- Schulich School of Engineering
- Worklund School of Education

☒ CHREB University of Calgary - Conjoint Health Research Ethics Board:

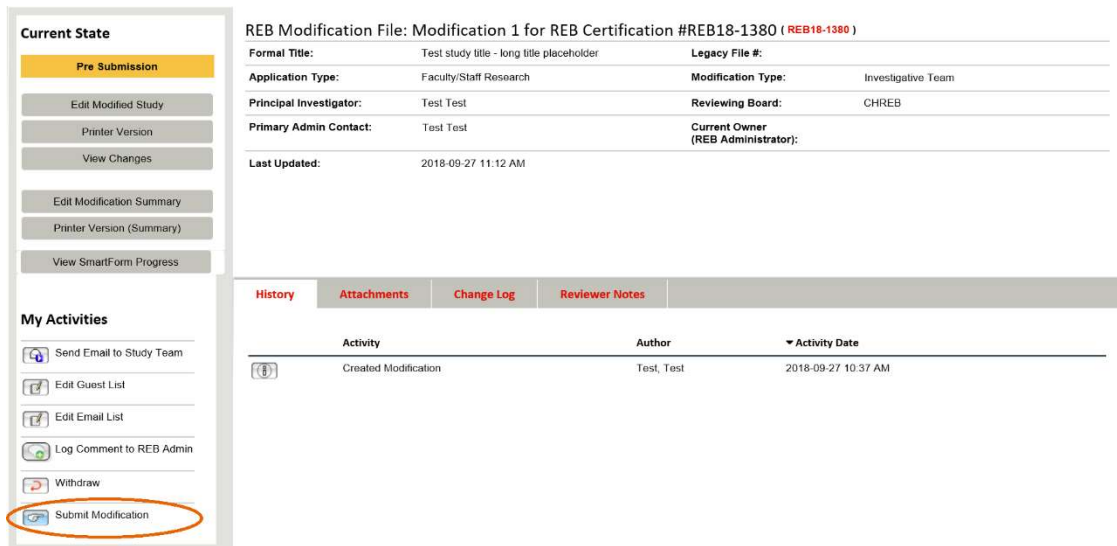
**Important!** Do not delete the previous version of the document, it will remain in the Document History.

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

### III. SUBMIT THE MODIFICATION FOR REVIEW

The Principal Investigator **and** members listed on the study team 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.



**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**

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		

**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 or the study team member must click **Submit Modification**.

- Once all required information has been entered, the Principal Investigator will be able to submit the application by clicking the 'Submit' activity button on the left-side menu of the certification workspace.
- 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.
- Please contact the IRISS Help Desk for additional support: [iriss.support@ucalgary.ca](mailto:iriss.support@ucalgary.ca) (403) 210-9300 or 1-855-222-2345.