

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

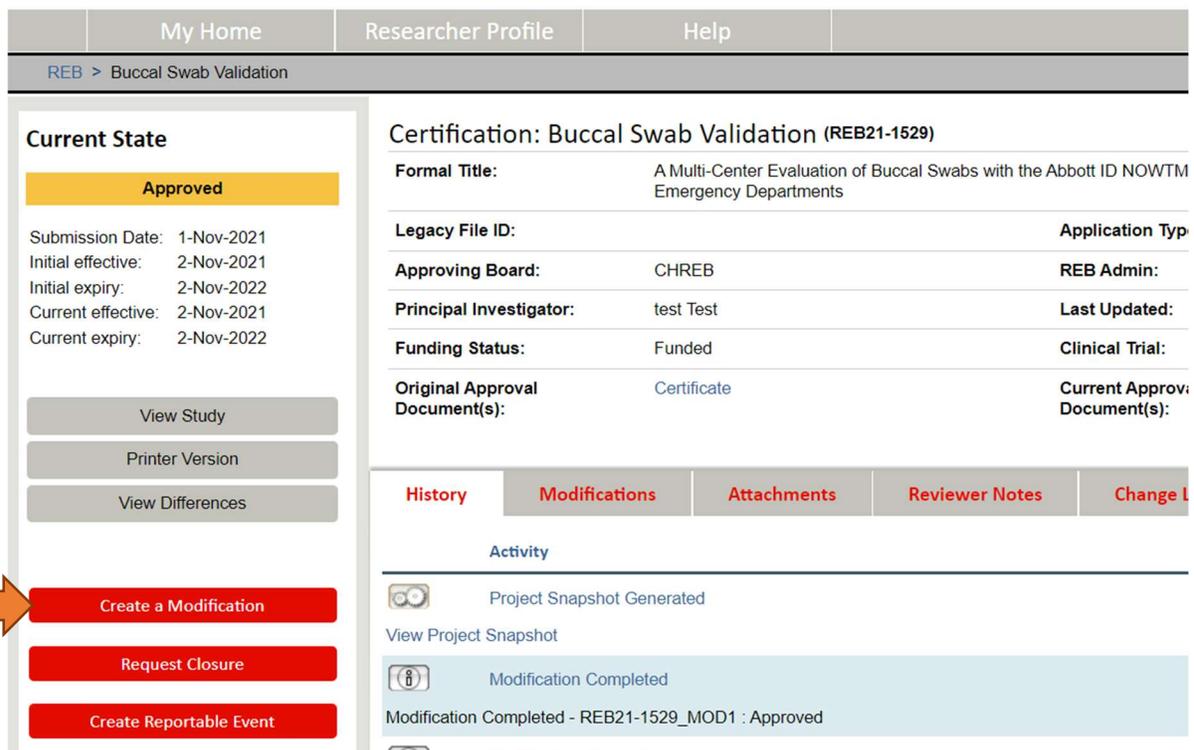
II - MODIFY THE STUDY

- 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.



My Home Researcher Profile Help

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

View Study
 Printer Version
 View Differences

Create a Modification

Request Closure

Create Reportable Event

Certification: Buccal Swab Validation (REB21-1529)

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

History
 Modifications
 Attachments
 Reviewer Notes
 Change L

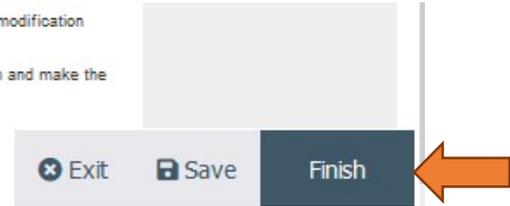
Activity

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

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.

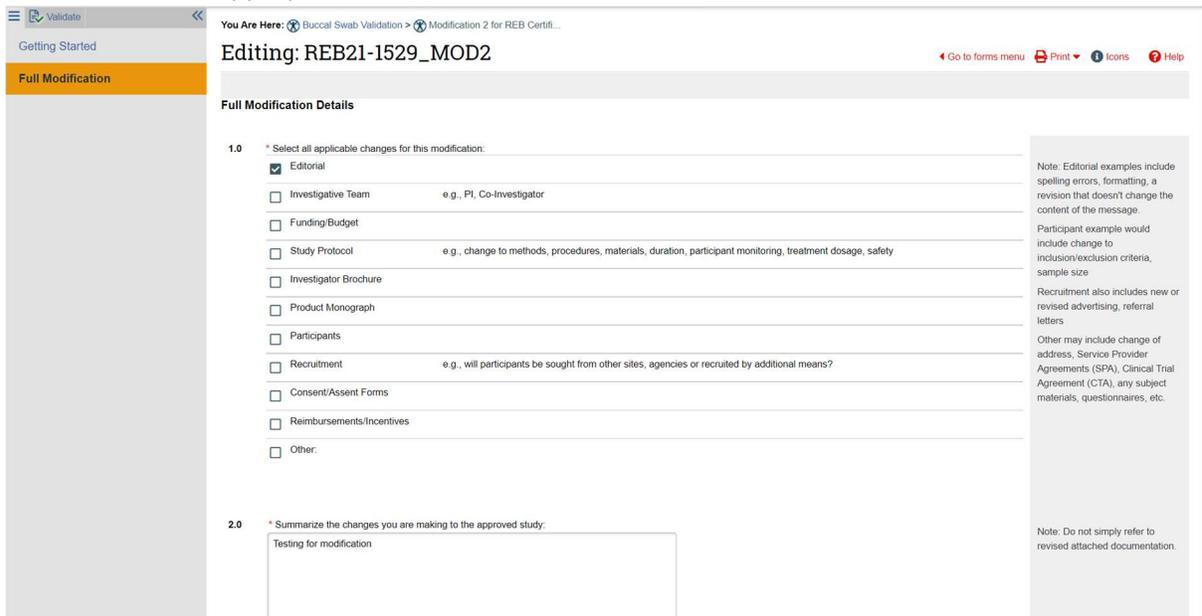


Click the 'Exit or Finish' button to save and exit this form. You will be directed to the workspace for this modification request.

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:

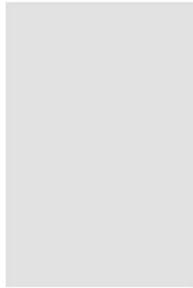
2.0 * Summarize the changes you are making to the approved study:

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.

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](#)

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.

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.

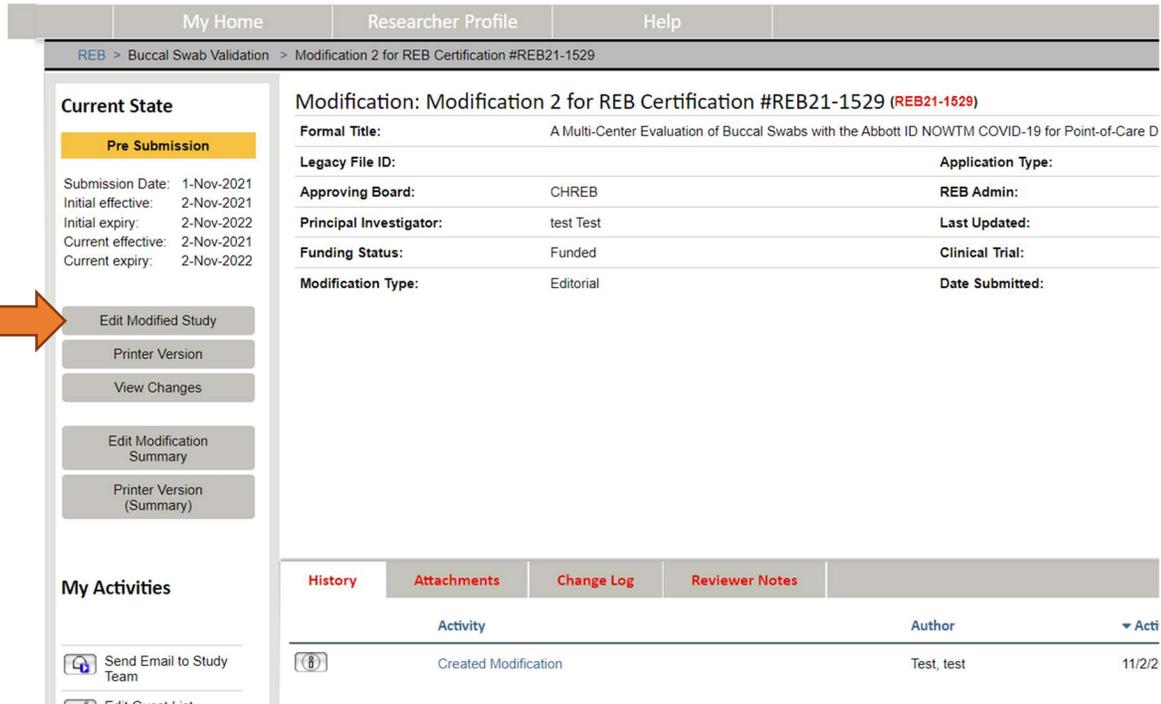
7. Click the 'Exit or Finish' button to close this form, this action does NOT submit the application.

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

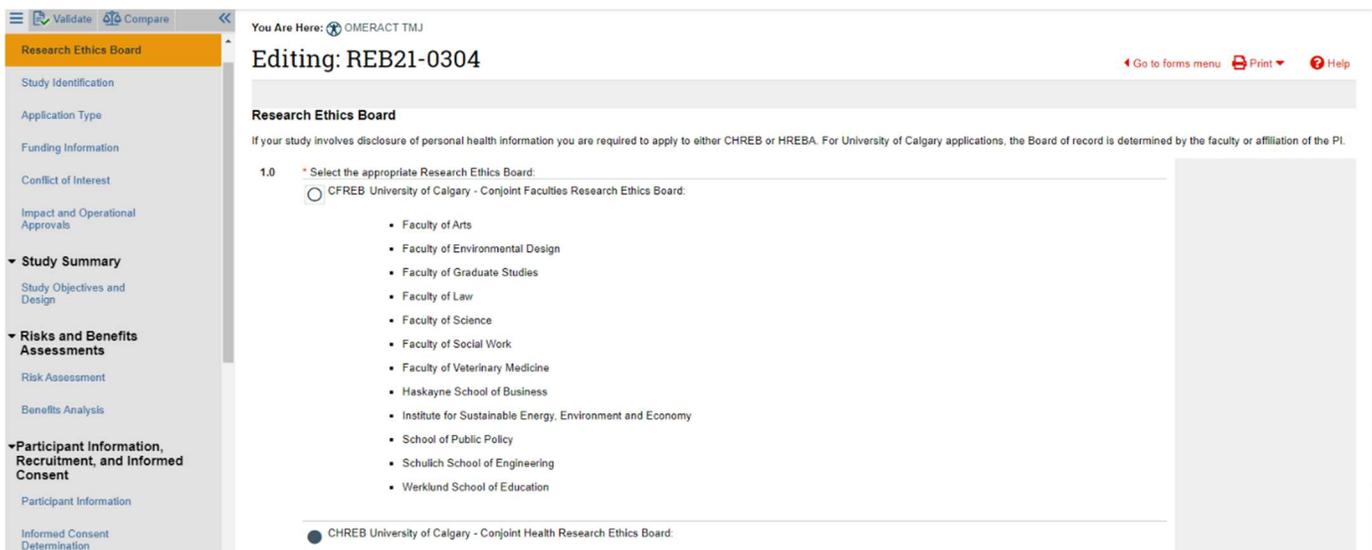
1. Click on **Edit Modified Study** on the left-hand side of the page.



The screenshot shows the IRISS interface for a study modification. At the top, there are navigation tabs: 'My Home', 'Researcher Profile', and 'Help'. Below this is a breadcrumb trail: 'REB > Buccal Swab Validation > Modification 2 for REB Certification #REB21-1529'. The main content area is divided into two columns. The left column, titled 'Current State', has a sub-section 'Pre Submission' with a yellow background. It lists submission and expiry dates. Below this list are four buttons: 'Edit Modified Study' (highlighted with an orange arrow), 'Printer Version', 'View Changes', and 'Edit Modification Summary'. Further down are 'Printer Version (Summary)' and 'My Activities' with a 'Send Email to Study Team' button. The right column shows the 'Modification: Modification 2 for REB Certification #REB21-1529 (REB21-1529)' details, including 'Formal Title', 'Legacy File ID', 'Approving Board' (CHREB), 'Principal Investigator' (test Test), 'Funding Status' (Funded), and 'Modification Type' (Editorial). At the bottom, there is a 'History' tab and a table with columns for 'Activity', 'Author', and 'Acti'. The table shows one entry: 'Created Modification' by 'Test, test' on '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' page in the IRISS system. The top navigation bar includes 'Validate', 'Compare', and 'You Are Here: OMERACT TMJ'. The left sidebar contains a navigation menu with categories like 'Study Identification', 'Application Type', 'Funding Information', 'Conflict of Interest', 'Impact and Operational Approvals', 'Study Summary', 'Risks and Benefits Assessments', and 'Participant Information, Recruitment, and Informed Consent'. The main content area is titled 'Editing: REB21-0304' and includes a 'Research Ethics Board' section. It contains a form with a question: '1.0 * Select the appropriate Research Ethics Board:'. There are two radio button options: 'CFREB University of Calgary - Conjoint Faculties Research Ethics Board' (unselected) and 'CHREB University of Calgary - Conjoint Health Research Ethics Board' (selected). A list of faculties is provided for the CFREB option, including 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, and Werkbund School of Education. At the bottom right, there are links for 'Go to forms menu', 'Print', and 'Help'.

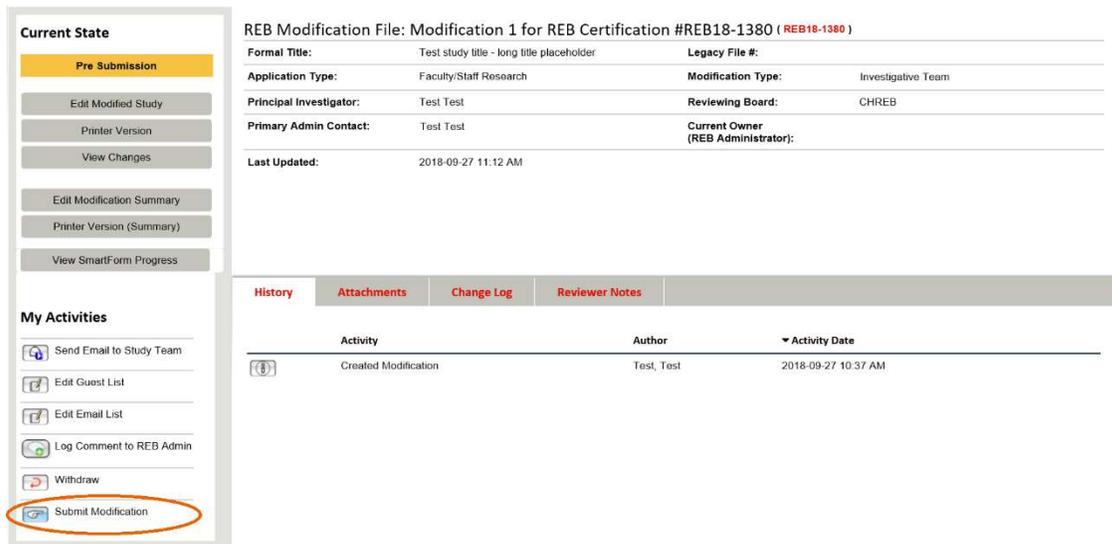
Important! Do not delete the previous version of the document, it will remain in the Document History.

- 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**)

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	Current Owner (REB Administrator):	
Last Updated:	2018-09-27 11:12 AM		

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 PI or the study team member will be able to submit the modification 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 (403) 210-9300 or 1-855-222-2345.