

VIEW CHANGES IN YOUR STUDY

This functionality is used when a PI or Study team want to view the changes that have been made to a study. This can be done in a number of states.

1. Log in to IRISS: <https://research.ucalgary.ca/iriss>
2. You will find the study under your **REB/Inbox** tab. Click on the name of the study to open the Study Workspace.

Current State

Changes Required by Delegated Approver - Admin Review

Submission Date: 4-Aug-2021
 Initial effective:
 Initial expiry:
 Current effective:
 Current expiry:

View Study

Printer Version

View Differences

Certification File (Initial Application)

To review the changes, click on **View Differences**, on the left hand side of the Study Workspace.

Modification File (Amendment to the Initial Application)

To review the changes, click on **View Changes**, on the left hand side of the Study Workspace.

My Home Researcher Profile Help

REB > Buccal Swab Validation > Modification 2 for REB Certification #REB21-1529

Current State

Changes Requested by ERO – Waiting For PI Response

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

Edit Modified Study

Printer Version

View Changes

Edit Modification Summary

Printer Version (Summary)

My Activities

- Send Email to Study Team
- Edit Guest List
- Edit Email List
- Log Comment to REB Admin
- Submit Changes

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

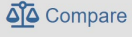
Formal Title:	A Multi-Center Evaluation of Buccal Swabs with the Abbott ID NOWTM COVID-19 for Point-of-Care Detection SARS-CoV-2 in Pediatric Emergency I		
Legacy File ID:		Application Type:	Faculty/Staff Research
Approving Board:	CHREB	REB Admin:	Maryam Tahir
Principal Investigator:	test Test	Last Updated:	2-Nov-2021
Funding Status:	Funded	Clinical Trial:	Yes
Modification Type:	Editorial	Date Submitted:	2-Nov-2021

History	Attachments	Change Log	Reviewer Notes
Activity			
Changes Requested by REB Administrator			Tahir, Maryam 11/2/2021 2:22 PM
1 Reviewer Notes Logged on Modification Study. 0 Reviewer Notes Logged on Modification Summary.			
An administrative review of your application has been completed by the CHREB. Please respond to all reviewer notes (under the Reviewer Notes tab) and have the Principal Investigator click "Changes" activity button. Thank you, Maryam			
Modification Submitted			Test, test 11/2/2021 2:18 PM
Created Modification			Test, test 11/2/2021 2:03 PM

IRISS –View Changes/Differences
 iriss.support@ucalgary.ca

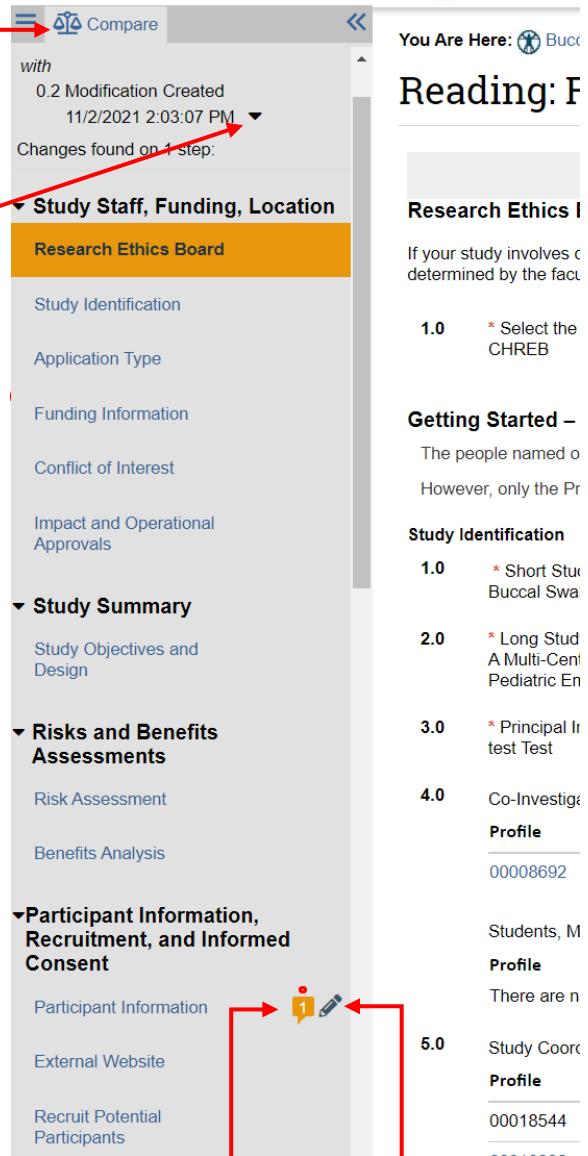
1

NOVEMBER 2021

Click on the  Compare button at the top of the navigation pane

Click on the down arrow next to the date

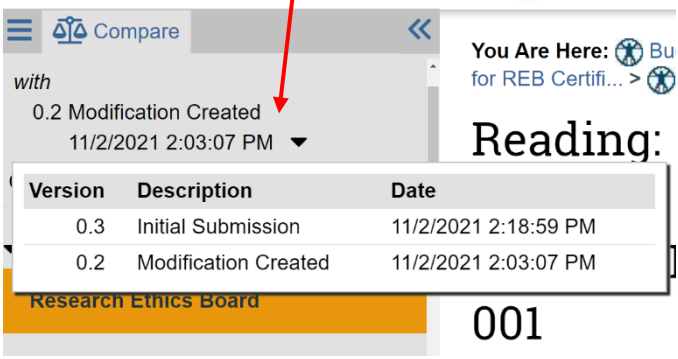
Select the appropriate version number to review changes made prior to that date. You may have to choose an earlier version to see all changes depending on the number of times the study went back and forth between the PI and reviewing Board.



The screenshot shows the 'Compare' dropdown menu with the following options:

- 0.2 Modification Created 11/2/2021 2:03:07 PM
- 0.3 Initial Submission 11/2/2021 2:18:59 PM
- 0.2 Modification Created 11/2/2021 2:03:07 PM

The 'Research Ethics Board' section is highlighted in orange. The 'Participant Information, Recruitment, and Informed Consent' section is also visible, with an orange comment bubble and a pencil icon next to the 'Participant Information' link.



Version	Description	Date
0.3	Initial Submission	11/2/2021 2:18:59 PM
0.2	Modification Created	11/2/2021 2:03:07 PM

3. Reviewer notes will appear as orange comment bubbles in the application. The pencil icon indicates that a change was made on that page of the application

4. The old value will show underneath the question in the grey box and the new value / wording will show above (new wording will be highlighted in **green**).

Participant Information, Recruitment, and Informed Consent

Participant Information 1

External Website

Recruit Potential Participants

Informed Consent Determination

Research Methods and Procedures

Research Methods and Procedures

Interviews, Focus Groups, Surveys and Questionnaires

Investigational Health Products

Health and Biological Specimen Collection

Chart Reviews

2882

6.0 Provide justification for sample size:
 Our sample size determination considered feasibility, likely prevalence, desired accuracy, and anticipated sensitivity. We determined that enrolling 2334 children would provide sufficient power, to confirm a sensitivity of 80% relative to the reference standard, assuming a prevalence of 3% and a confidence window of $\pm 10\%$. After adjusting for 10% protocol non-adherence (e.g. inadequate or indeterminate specimens) a total of 2882 enrolled children will be required. In total, 70 positive children will need to be enrolled on gold standard testing. The final sample size recruited will be adjusted based on the number of children who are positive and will be reduced or expanded based on our positivity rate which will evolve over time across the country.

The local sample size will be 800.

test Test • modified 3 minutes ago • version 0.3+ (Initial Submission)

Old Value:

Our sample size determination considered feasibility, likely prevalence, desired accuracy, and anticipated sensitivity. We determined that enrolling 2334 children would provide sufficient power, to confirm a sensitivity of 80% relative to the reference standard, assuming a prevalence of 3% and a confidence window of $\pm 10\%$. After adjusting for 10% protocol non-adherence (e.g. inadequate or indeterminate specimens) a total of 2882 enrolled children will be required. In total, 70 positive children will need to be enrolled on gold standard testing. The final sample size recruited will be adjusted based on the number of children who are positive and will be reduced or expanded based on our positivity rate which will evolve over time across the country.

7.0 * Does your research involve First Nations, Inuit or Métis Peoples of Canada or other Indigenous communities? This would include:

- research conducted on First Nations, Inuit or Métis lands;
- recruitment criteria that include Indigenous identity as a factor for the entire study or for a subgroup in the study;
- research that seeks input from participants regarding a community's cultural heritage, artefacts, traditional knowledge or unique characteristics;
- research in which Indigenous identity or membership in an Indigenous community is used as a variable for the purpose of analysis of the research data;
- interpretation of research results that will refer to Indigenous communities, peoples, language, history or culture.
- other research activities that may impact the welfare of Indigenous communities.

Yes No

Note: If the new value is a *number* or a *yes/no* response, it may not be highlighted in green.

Interviews, Focus Groups, Surveys and Questionnaires

Investigational Health Products

Health and Biological Specimen Collection

Chart Reviews

5.0 Participants

* 5.1 How many participants do you expect to recruit (including controls, if applicable)? 1

400

test Test • modified 17 minutes ago • version 0.3 (Initial Submission)

Old Value:

800

Use the navigation pane on the left-hand side to view all changes made, and then click **Exit** at the bottom of the page to bring you back to the study workspace.