MAKE REQUESTED CHANGES TO A STUDY/APPLICATION

This document entails how to make changes to your study for the change requests from REB administrators or Board.

This involves **two** steps:

    I.   **Make requested changes to study**
- Edit the desired pages of application (To navigate use the '**Edit Study**' button on left-hand side of the page).
- Save the Changes.

    II.   **Respond to Reviewer notes**

I. HOW TO MAKE REQUESTED CHANGES

1. You will receive an email from the IRISS system indicating that changes or clarifications are required. Click on the Ethics ID link in the email beside Study ID to go directly to the Study Workspace.

> Clarifications or changes are required for the request indicated below by Saturday, August 11, 2018.
>
> General guidance:
>
> - Click the Study ID link or login to IRISS, under the **INBOX tab**, navigate to the study.
> - Under the **Reviewer Notes tab**, address each item and make any changes in the application, if applicable.
> - **The PI must submit the changes by clicking on the 'Submit Changes' button under My Activities.**
>
> Principal Investigator: *<PI name>*
> Short Study Title: *<Short study title>*
> Long Study Title: *<Long study title>*
> Study Id: **REB18-1388**

2. Alternatively, you can enter the Study Workspace directly from your Personal Home page in IRISS. The study will show in your **INBOX** - click on the study name to open the Study Workspace.

Page for Test Test

Inbox	REB	Templates	REB Protocols Research List	ACC Protocols Research List	

Filter ❓ | ID ▼ | Enter text to search for | Go ➕ Add Filter ✖ Clear All

ID	Name	Short Title	▼ Date Modified	Type	Legacy File#	State	Last State Change
⊗ REB18-1388	Test Study title III		2018-10-18 11:05 AM	REB Certification		Changes Requested by ERO-Waiting For PI Response	2018-08-10 6:11 AM

3. **History Tab** – shows Changes Requested and indicates how many **Reviewer Notes** have been logged and gives further instructions regarding making changes.
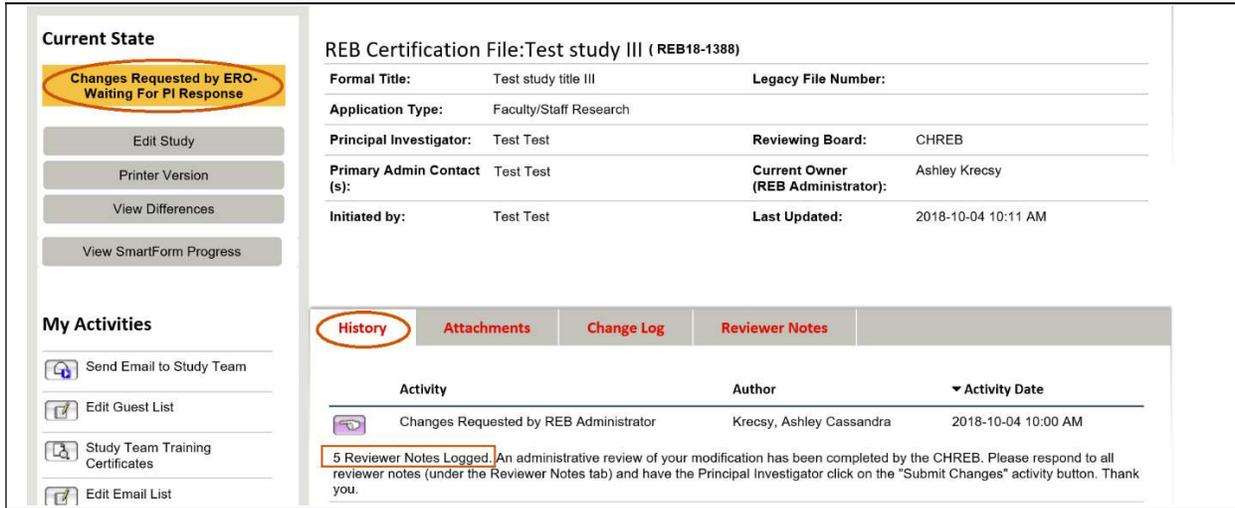
Current State

Changes Requested by ERO-Waiting For PI Response

Edit Study

Printer Version

View Differences

View SmartForm Progress

My Activities

Send Email to Study Team

Edit Guest List

Study Team Training Certificates

Edit Email List

REB Certification File:Test study III (REB18-1388)

Formal Title:	Test study title III	Legacy File Number:	
Application Type:	Faculty/Staff Research		
Principal Investigator:	Test Test	Reviewing Board:	CHREB
Primary Admin Contact (s):	Test Test	Current Owner (REB Administrator):	Ashley Krecsy
Initiated by:	Test Test	Last Updated:	2018-10-04 10:11 AM

History	Attachments	Change Log	Reviewer Notes

Activity	Author	▼ Activity Date
Changes Requested by REB Administrator	Krecsy, Ashley Cassandra	2018-10-04 10:00 AM

5 Reviewer Notes Logged. An administrative review of your modification has been completed by the CHREB. Please respond to all reviewer notes (under the Reviewer Notes tab) and have the Principal Investigator click on the "Submit Changes" activity button. Thank you.

4. Click on the **Reviewer Notes** tab to view the requested changes/clarifications. In this example, the note is a **Change Request** on the **Documentation** page.
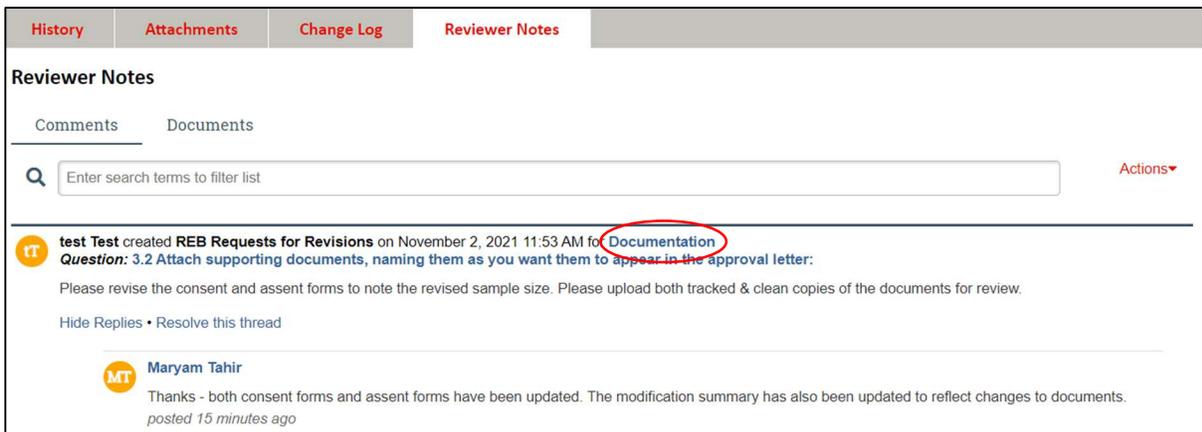
History	Attachments	Change Log	Reviewer Notes

Reviewer Notes

Comments	Documents

🔍 Enter search terms to filter list   Actions▼

tT **test Test** created **REB Requests for Revisions** on November 2, 2021 11:53 AM for **Documentation**
Question: 3.2 Attach supporting documents, naming them as you want them to appear in the approval letter:

Please revise the consent and assent forms to note the revised sample size. Please upload both tracked & clean copies of the documents for review.

Hide Replies • Resolve this thread

MT **Maryam Tahir**

Thanks - both consent forms and assent forms have been updated. The modification summary has also been updated to reflect changes to documents.
posted 15 minutes ago

5. To get to the appropriate page in the study, navigate to the left hand side of the screen, click **Edit Study,** and use the scroll pane to navigate to the page with the comment icon.
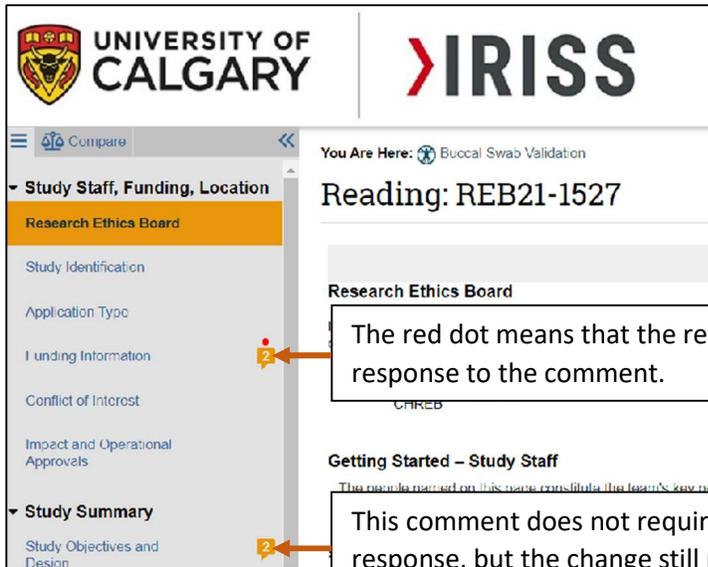
The red dot means that the reviewer has requested a response to the comment.

This comment does not require a response, but the change still needs to be made in the application.

Click on the comment bubble to view the reviewer note.
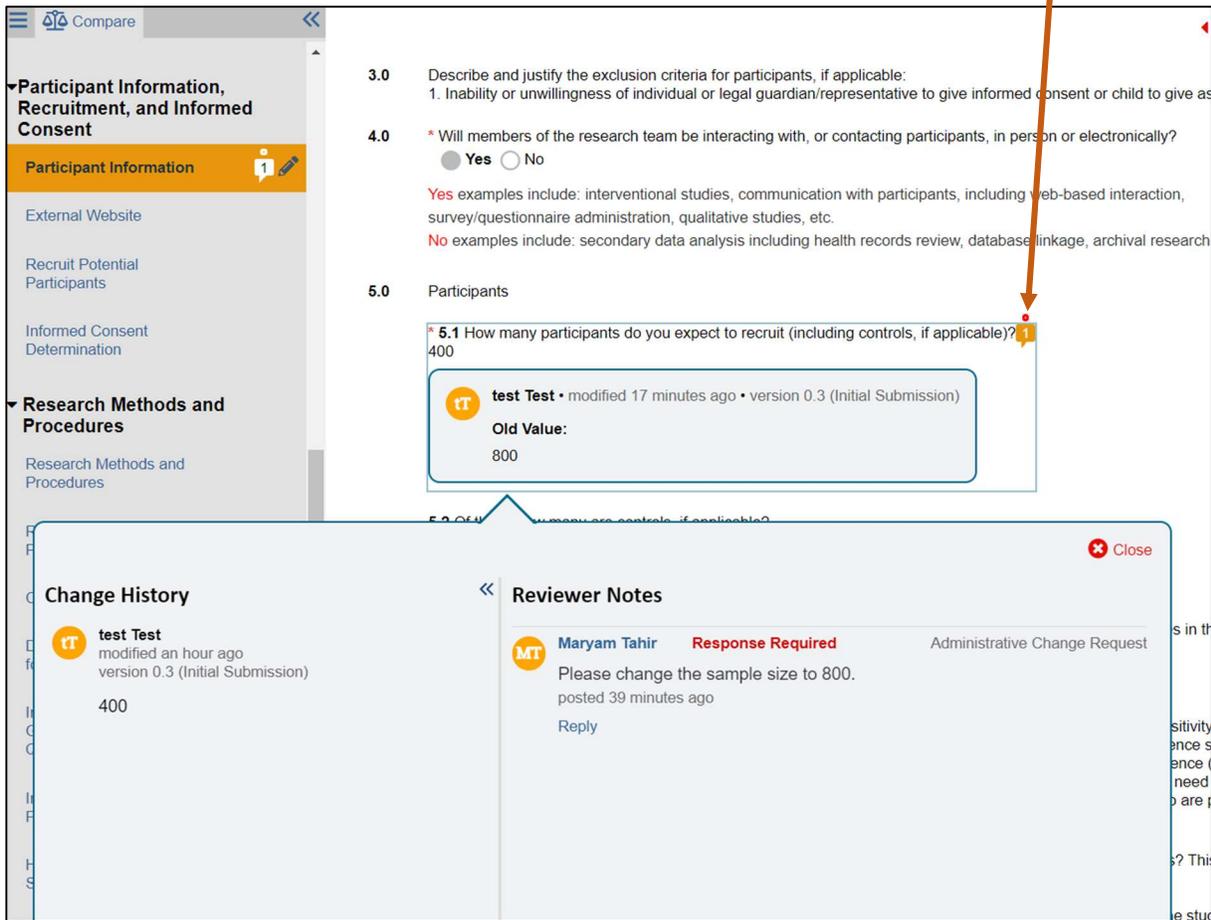
6. Make the necessary changes on corresponding pages as per the reviewer notes.

II. HOW TO RESPOND TO REVIEWER NOTES

1. If the reviewer note indicates that a there is a **Response Required**, click on Reply.
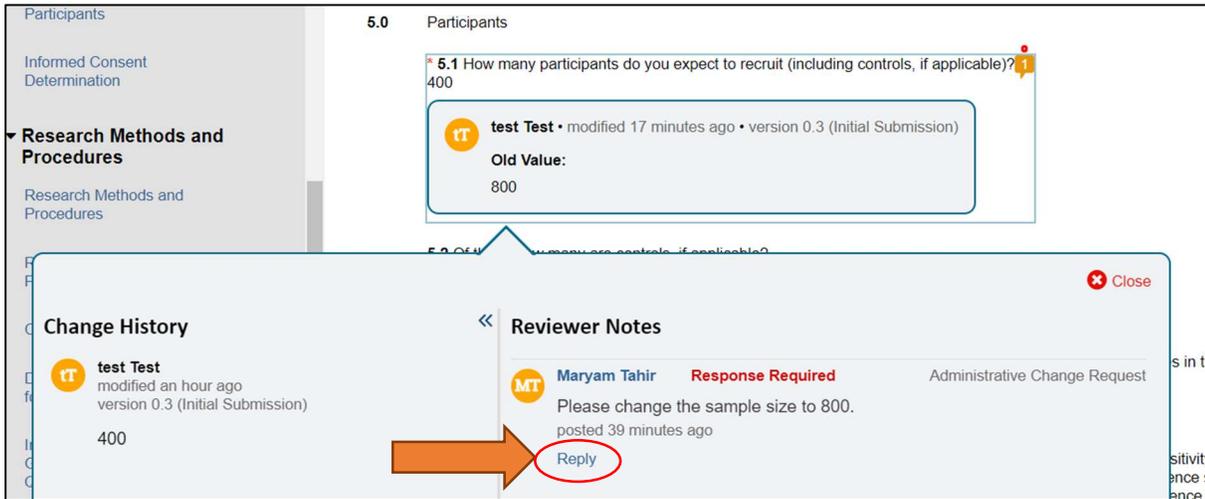
2. A response box will open for you to add your comments. Click on the **OK** button in the bottom right to save your response, then click **Close** to close the comment window.
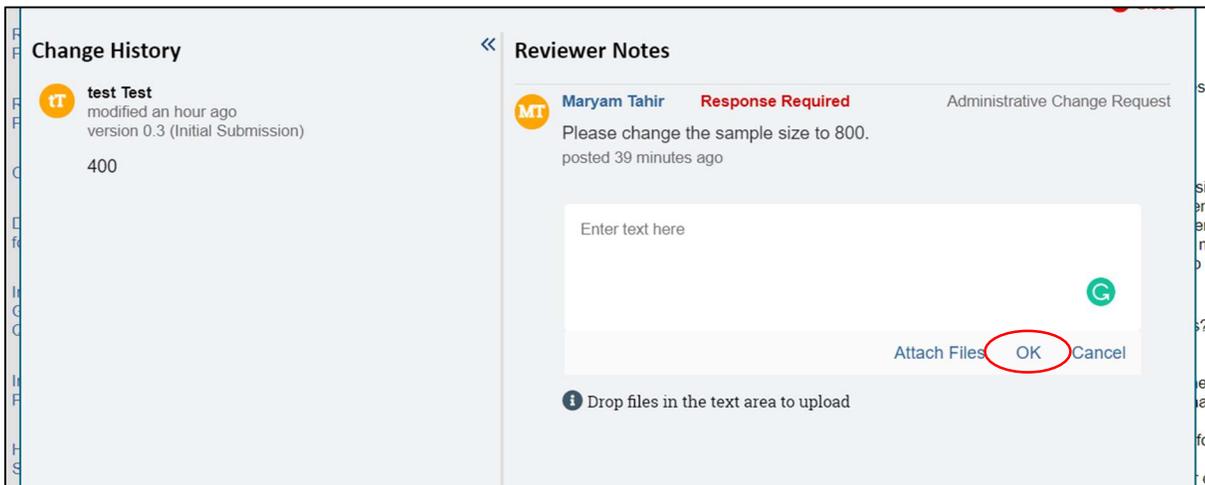
3. Once completed, your response will show in the box underneath the original request.
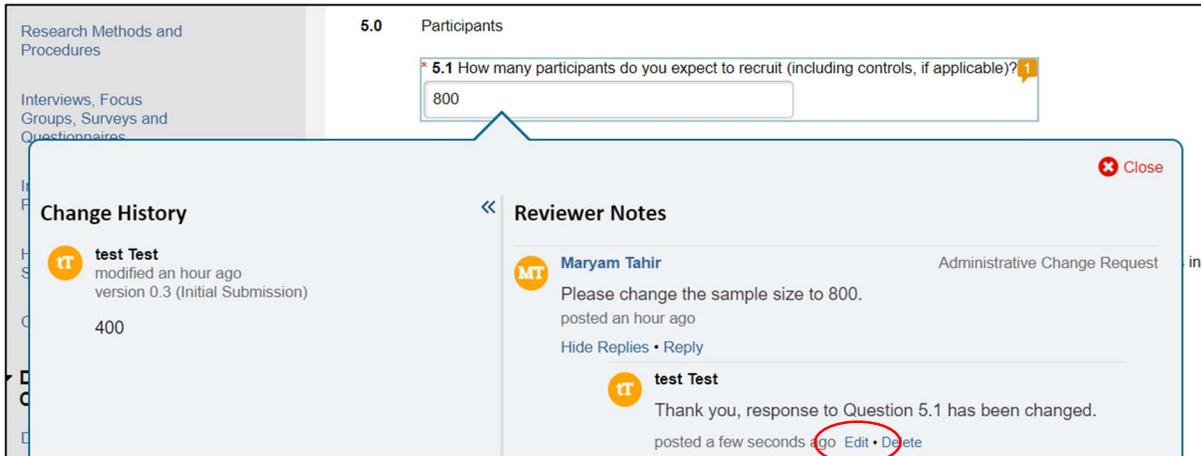
4. If you click on **OK** and realize you would like to add/ change your response, click on **Edit** to re-open the response box and make your changes.

You can also **Delete** your response to the comment and start again.

5. Once you have made all the appropriate changes and responded to all Reviewer Notes, click on **Save & Close** at the bottom of the page.

6. This will take you back to the Study Workspace. To submit the changes, the PI will click on the **Submit Changes** button under **My Activities** on the left had side of the page.

HOW DO I KNOW MY CHANGES HAVE BEEN SUBMITTED?

You will know the changes have been submitted when:

Current state of the study changes (in this example it changes from *Changes Required by ERO - Waiting for PI Response* - to - *Under Ethics Resource Officer Review*)

- History Tab shows **Changes Submitted**.