

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 either page links under **Reviewer Notes** tab or '**Edit Study**' button on left-hand side of the page).
- Save the Changes.

II. Respond to Reviewer notes

- Click on link "**Click here to respond**" (under Reviewer Notes tab) and provide a response.

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 ²							
ID	Enter text to search for			Go	+ Add Filter	x 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

- 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.





- Click on the **Reviewer Notes** tab to view the requested changes/clarifications. In this example, the first note is a **Change Request** on **Health and Biological Specimen Collection** page and the second note is a **Request for Clarification** on the **Data Identifiers** page.

To get to the appropriate page in the study, click on the page name link beside **Jump To:**
Make the necessary changes on corresponding pages as per the reviewer notes.

History Attachments Change Log **Reviewer Notes**

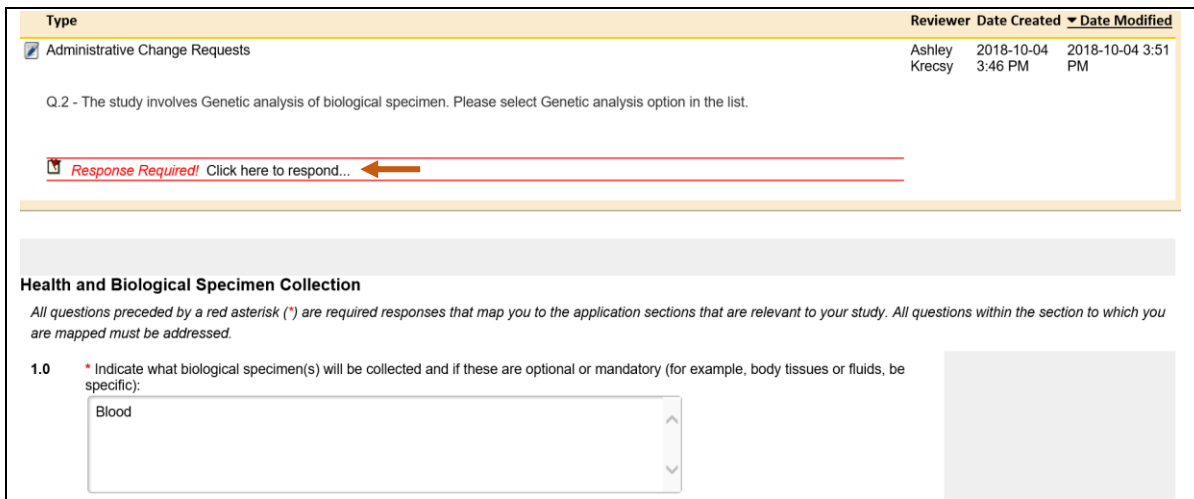
Reviewer Notes

Filter ? Type Go + Add Filter x Clear All

Type	Reviewer	Date Created	Date Modified
Administrative Change Requests Jump To: Health and Biological Specimen Collection  Click on this page link to go to that page	Ashley Krecsy	2018-10-04 3:46 PM	2018-10-04 3:51 PM
Q.2 - The study involves Genetic analysis of biological specimen. Please select Genetic analysis option in the list.			
 Response Required! Click here to respond...			
Administrative Request for Clarification Jump To: Data Identifiers  Click on this page link to go to that page	Ashley Krecsy	2018-10-04 3:42 PM	2018-10-04 3:42 PM
Q.5 - Will the data in this study be linked with any other studies. If yes, please complete Q.5 on this page.			
 Response Required! Click here to respond...			

II. HOW TO RESPOND TO REVIEWER NOTES

1. Once the change has been made, click on link “**Click here to respond**”.

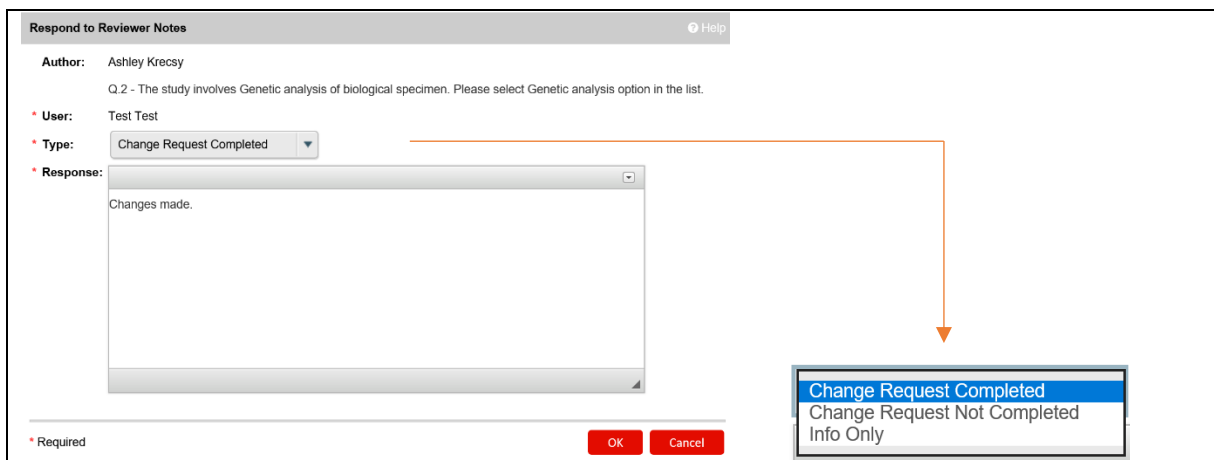


The screenshot shows a table with columns: Type, Reviewer, Date Created, and Date Modified. The first row shows 'Administrative Change Requests' by 'Ashley Krecsy' on '2018-10-04 3:46 PM'. Below the table, a note reads: 'Q.2 - The study involves Genetic analysis of biological specimen. Please select Genetic analysis option in the list.' A red banner with a warning icon and the text 'Response Required! Click here to respond...' is displayed. Below this, a section titled 'Health and Biological Specimen Collection' contains a question '1.0 * Indicate what biological specimen(s) will be collected and if these are optional or mandatory (for example, body tissues or fluids, be specific):'. A text input field contains the word 'Blood'.

2. A response box will open, the system defaults the Type: to **Change Request Completed** In the response box, add your comments. If no comments are necessary, type in ‘changes made’ or ‘changes completed’ and click on the **OK** button in the bottom right hand corner.

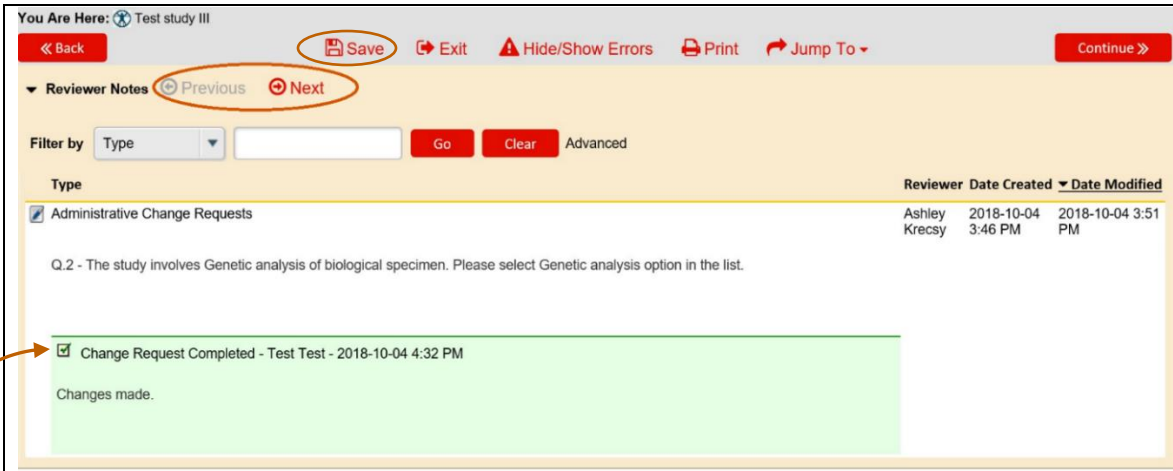
If you are not making the requested changes, choose Type: **Change Request Not Completed**. Indicate the rationale for not making the requested change in the response box and click on the **OK** button in the bottom right hand corner.

If the Reviewer Note is a **Request for Clarification** and no change is necessary, choose Type: **Info Only**. Add your clarification notes in the response box and click on the **OK** button in the bottom right hand corner.



The screenshot shows the 'Respond to Reviewer Notes' dialog box. It includes fields for 'Author: Ashley Krecsy' and 'User: Test Test'. The 'Type' dropdown is set to 'Change Request Completed'. The 'Response' text area contains 'Changes made.' At the bottom, there are 'OK' and 'Cancel' buttons. A red asterisk indicates required fields. A blue box with a white arrow points to the 'Change Request Completed' option in the dropdown menu.

- Once completed, your response will show in green underneath the original request. Save the page by clicking on **SAVE** at the top of the page. Click on **NEXT** or **PREVIOUS** to move to the next/previous Change Request.



You Are Here: Test study III

« Back Save Exit Hide/Show Errors Print Jump To » Continue »

▼ Reviewer Notes Previous Next

Filter by Type [] Go Clear Advanced

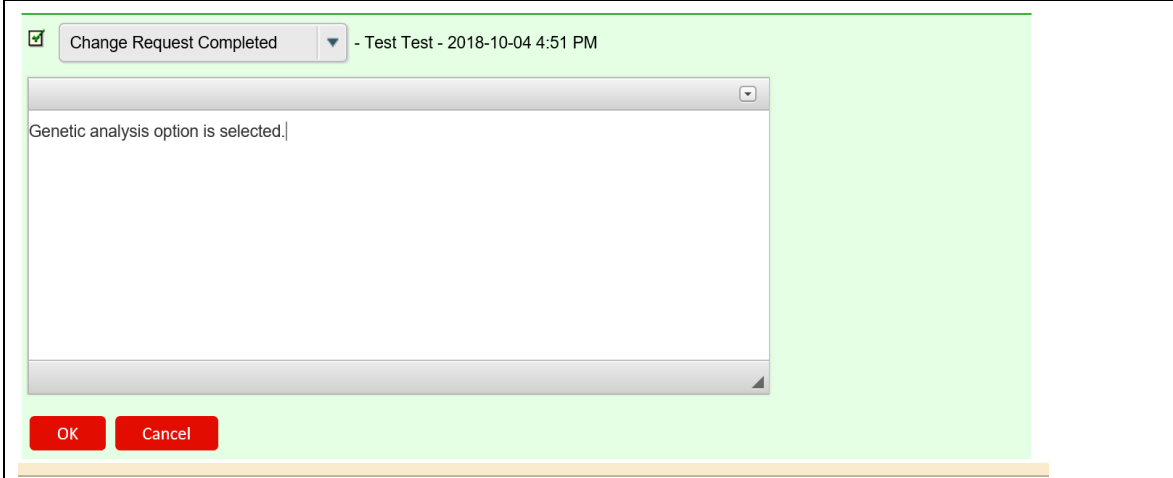
Type	Reviewer	Date Created	Date Modified
Administrative Change Requests	Ashley Krecsy	2018-10-04 3:46 PM	2018-10-04 3:51 PM

Q.2 - The study involves Genetic analysis of biological specimen. Please select Genetic analysis option in the list.

☒ Change Request Completed - Test Test - 2018-10-04 4:32 PM

Changes made.

- If you click on **OK** and realize you would like to add/ change your response, click on **Change Request Completed** to re-open the response box and make your changes. Click on **OK** in the bottom left hand corner. Once you have made all the appropriate changes and responded to all Reviewer Notes, click on **Save** and **Exit** at the top or bottom of the page.

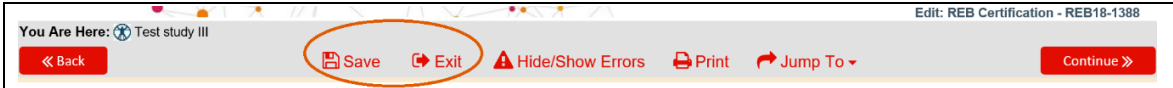


☒ Change Request Completed - Test Test - 2018-10-04 4:51 PM

Genetic analysis option is selected.

OK Cancel

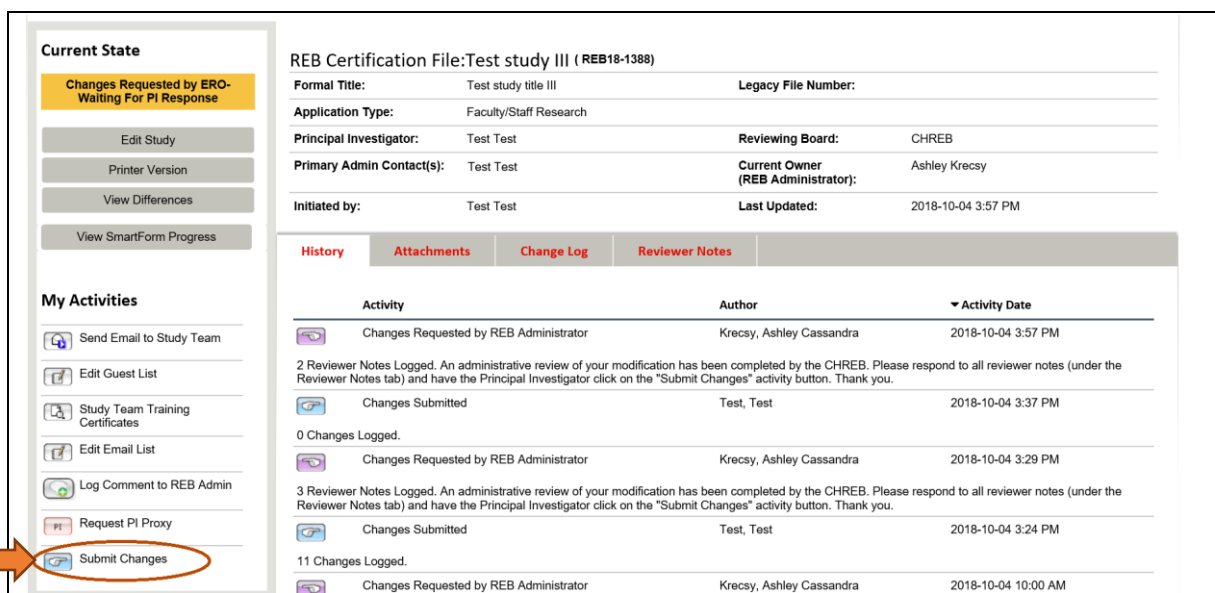
- Once you have made all the appropriate changes and responded to all Reviewer Notes, click on **Save/Exit** at the top or bottom of the of the page.



You Are Here: Test study III Edit: REB Certification - REB18-1388

« Back Save Exit Hide/Show Errors Print Jump To » Continue »

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 hand side of the page.



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
- Log Comment to REB Admin
- Request PI Proxy
- Submit Changes**

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 3:57 PM

History | Attachments | Change Log | Reviewer Notes

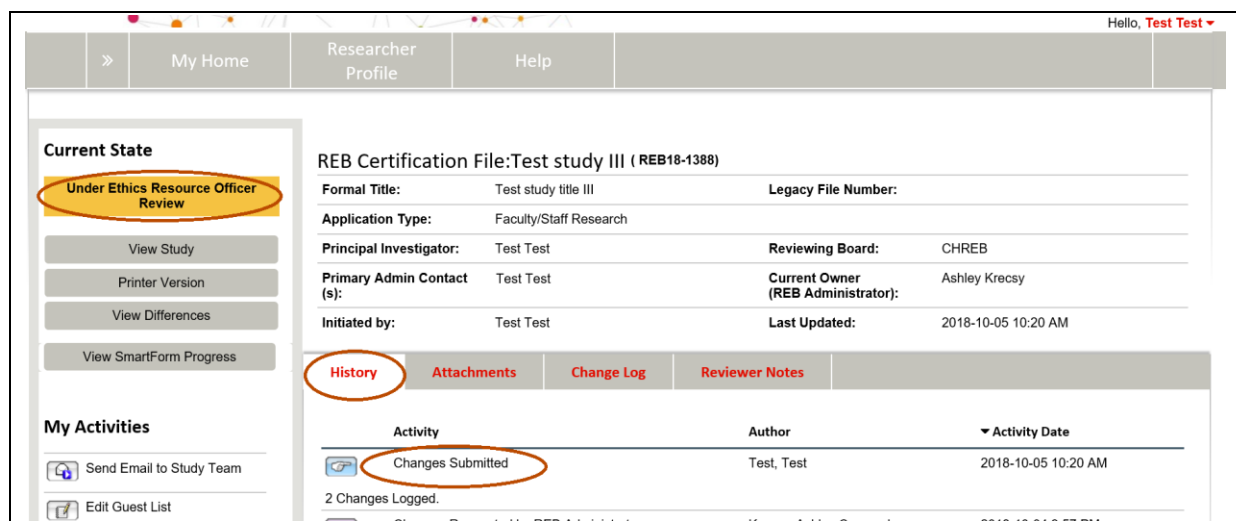
Activity	Author	Activity Date
Changes Requested by REB Administrator	Krecsy, Ashley Cassandra	2018-10-04 3:57 PM
2 Reviewer Notes Logged. An administrative review of your modification has been completed by the CHREB. Please respond to all reviewer notes (under the Reviewer Notes tab) and have the Principal Investigator click on the "Submit Changes" activity button. Thank you.		
Changes Submitted	Test, Test	2018-10-04 3:37 PM
0 Changes Logged.		
Changes Requested by REB Administrator	Krecsy, Ashley Cassandra	2018-10-04 3:29 PM
3 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.		
Changes Submitted	Test, Test	2018-10-04 3:24 PM
11 Changes Logged.		
Changes Requested by REB Administrator	Krecsy, Ashley Cassandra	2018-10-04 10:00 AM

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 Requested by ERO - Waiting for PI Response** - to - **Under Ethics Resource Officer Review**)

- History Tab shows **Changes Submitted**.



My Home | Researcher Profile | Help | Hello, Test Test

Current State

Under Ethics Resource Officer Review

View Study
Printer Version
View Differences
View SmartForm Progress

My Activities

- Send Email to Study Team
- Edit Guest 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:	2018-10-05 10:20 AM

History | Attachments | Change Log | Reviewer Notes

Activity	Author	Activity Date
Changes Submitted	Test, Test	2018-10-05 10:20 AM
2 Changes Logged.		