

)IRISS

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: <u>REB18-1388</u>

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.

				1 m m				
Inbox	REB	Templates	REB Protoco	ols Research List	ACC Pr	otocols F	Research List	
Filter 🔞	ID	Enter tex	t to search for	Go +	Add Filter 🗙 C	lear All		
			Short	▼ Date	-	Legacy	State	Last State
ID	N	ame	Title	Modified	Туре	File#	State	Change



>IRISS

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

Changes Requested by ERO-	Formal Title:	Test study title III	Legacy File Number:	
Walking For Fi Response	Application Type:	Faculty/Staff Research		
Edit Study	Principal Investigator:	Test Test	Reviewing Board:	CHREB
Printer Version	Primary Admin Contact (s):	Test Test	Current Owner (REB Administrator):	Ashley Krecsy
View Differences	Initiated by:	Test Test	Last Updated:	2018-10-04 10:11 AM
y Activities	History Attach	iments Change Log	Reviewer Notes	
y Activities	History Attach	ments Change Log	Reviewer Notes	▼ Activity Date
y Activities Send Email to Study Team G Edit Guest List	History Attach	ested by REB Administrator	Reviewer Notes Author Krecsy, Ashley Cassandra	✓ Activity Date 2018-10-04 10:00 AM
y Activities Send Email to Study Team Edit Guest List Study Team Training Certificates	History Attach	uments Change Log	Reviewer Notes Author Krecsy, Ashley Cassandra modification has been completed by	✓ Activity Date 2018-10-04 10:00 AM (the CHREB, Please respond to all

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.

Hist	ory	Attachments	Change Log	Reviewer Notes		
Revie	wer No	otes				
Con	nments	Documents				
Q	Enter se	earch terms to filter list				Actions•
	test Test Question	created REB Request a: 3.2 Attach supportin	ts for Revisions on Non ng documents, namin	ovember 2, 2021 11:53 AM t ng them as you want them	o Documentation to a ppear in the approval letter:	
	Please re	evise the consent and a	ssent forms to note the	e revised sample size. Plea	se upload both tracked & clean copies of the documents for review.	
1	Hide Rep	lies • Resolve this three	ad			
		Maryam Tahir				
		Thanks - both cons posted 15 minutes	sent forms and assent ago	forms have been updated.	The modification summary has also been updated to reflect changes to docu	ments.
·						



>IRISS

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.





)IRISS

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.

Participant	S	5.0 Participar	ts	
Informed C Determinat	Consent tion	* 5.1 How 400	many participants do you expect to recruit (including controls, if applicable)?	
 Research Procedures Research I Procedures F 	h Methods and res Methods and s		est Test • modified 17 minutes ago • version 0.3 (Initial Submission) Did Value: 300 Vumeeu ee eestede if engliested)
c Chang	ge History	«	Reviewer Notes	
E T	test Test modified an hour ago version 0.3 (Initial Submission) 400		Maryam Tahir Response Required Administrative Change Request Please change the sample size to 800. posted 39 minutes ago Reply	s in th

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.

F	Change History «	Revi	ewer Notes		
F	modified an hour ago	MT	Maryam Tahir Response Required	Administrative Change Request	5
F	version 0.3 (Initial Submission)		Please change the sample size to 800		
C	400		posted 39 minutes ago		sit
E			Enter text here		en en
19					ne a
				C	
C				Attach Files OK Cancel	?
li			B Drop files in the text area to upload		e
			Top mes in the text area to uproau		fo
T UJ					0



)IRISS

3. Once completed, your response will show in the box underneath the original request.

Research Methods and Procedures Interviews, Focus Groups, Surveys and Questionnaires	5.0 Participants * 5.1 How n 800	ts many participants do you expect to recruit (including controls, if ap	plicable)?
Change History test Test modified an hour ago version 0.3 (Initial Submission) C 400	«	Reviewer Notes Maryam Tahir Please change the sample size to 800. posted an hour ago Hide Replies • Reply	dministrative Change Request in t
		test Test Thank you, response to Question 5.1 posted a few seconds to Edit • Dete	has been changed.

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.

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

Documentation Documentation				
Final Page				
		🛚 Exit	B Save	Save & Close
	マート 「「「」」」でのUS 世界 画 EG 「 」 「 」」でのUS 世界 画 EG 「 」 「 「 」 「 」 「 」 」 「 」 」 「 」 」 「 」 」 「 」 」 「 」 」 」 「 」		8	

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.

Changes Dequested by EDO.	Eormal Title:	Test study title III	Legnov File Number	
Waiting For PI Response	Formal flue:	rest study title in	Legacy File Number:	
	Application Type:	Faculty/Staff Research		
Edit Study	Principal Investigator:	Test Test	Reviewing Board:	CHREB
Printer Version	Primary Admin Contac	t(s): Test Test	Current Owner (REB Administrator)	Ashley Krecsy
View Differences	Initiated by:	Initiated by: Test Test		2018-10-04 3:57 PM
View SmartForm Progress	History Atta	chments Change Log	Reviewer Notes	
My Activities	Activity		Author	✓ Activity Date
Send Email to Study Team	Changes R	equested by REB Administrator	Krecsy, Ashley Cassandra	a 2018-10-04 3:57 PM
Edit Guest List	2 Reviewer Notes Logg Reviewer Notes tab) an	ed. An administrative review of you d have the Principal Investigator of	r modification has been completed by the CHRE ick on the "Submit Changes" activity button. Tha	EB. Please respond to all reviewer notes (under the ink you.
Study Team Training Certificates	Changes S	ubmitted	Test, Test	2018-10-04 3:37 PM
Edit Email List	0 Changes Logged.			
	Changes R	equested by REB Administrator	Krecsy, Ashley Cassandra	a 2018-10-04 3:29 PM
	1000 N 1000 N	ed. An administrative review of vor	r modification has been completed by the CHRE	EB. Please respond to all reviewer notes (under the
Log Comment to REB Admin	3 Reviewer Notes Logg Reviewer Notes tab) an	d have the Principal Investigator of	ick on the "Submit Changes" activity button. That	ink you.



>IRISS

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**.

	IN INV			Hello, Test T
urrent State	REB Certification	File:Test study III (REE	318-1388)	
Under Ethics Resource Officer	Formal Title:	Test study title III	Legacy File Number:	
Review	Application Type:	Faculty/Staff Research		
View Study	Principal Investigator:	Test Test	Reviewing Board:	CHREB
Printer Version	Primary Admin Contact (s):	Test Test	Current Owner (REB Administrator):	Ashley Krecsy
View Differences	Initiated by:	Test Test	Last Updated:	2018-10-05 10:20 AM
View SmartForm Progress	History Attach	ments Change Log	Reviewer Notes	
My Activities	Activity		Author	▼ Activity Date
Send Email to Study Team	Changes Subr	nitted	Test, Test	2018-10-05 10:20 AM
Edit Guest List	2 Changes Logged.			
		A REPORT OF A REPORT OF		0010 10 010 57 511