

Responding to Clarifications in eCompliance

STEP 1: To access your study, go to ecompliance.ku.edu and log in using your KU ID and password. The system will default to your eCompliance inbox. The study that requires clarifications will be located here. Click on the study name to view the clarifications.

The screenshot shows the 'My Current IRB Actions' section of the eCompliance system. A table lists the following study:

ID	Name	SmartForm	Execute Activity	Date Created	Date Modified	State	Owner	PI Action Required
STUDY0000043	Study Test 1	[Edit]	[Execute]	7/8/2013 10:32 AM	7/15/2013 9:31 AM	Clarification Requested (Designated Review)		no

STEP 2: Once in the study, the “History” tab will show the clarifications requested from an HSCL coordinator. He/she will outline exactly what needs to be clarified in order to gain approval to the study.

The screenshot shows the study details for 'STUDY0000043: Study Test 1'. The 'History' tab is active, displaying a list of activities. The following activity is highlighted with a yellow circle:

Activity	Author	Activity Date
Clarification Requested by Designated Reviewer	Dyson Elms, Stephanie Lynn	7/15/2013 9:31 AM CDT
Pre-Review Submitted	Dyson, Elms, Stephanie Lynn	7/15/2013 9:28 AM CDT
Submitted	Anderson, Anita	7/8/2013 10:45 AM CDT
Study Created	Anderson, Anita	7/8/2013 10:32 AM CDT

The highlighted activity includes the following instructions:

1. Please make changes to the consent form and resubmit revised version.
2. Submit copies of survey.
3. Some additional changes.

STEP 3: The “Edit Study” button allows you to edit the original application and make any changes. Resubmit documents on the appropriate page (consent form, recruitment materials, or application), or make other changes as required by the reviewer.

Home IRB COI
 IRB > IRB Submissions > Study Test 1

STUDY00000043: Study Test 1
 Principal investigator: Anita Anderson
 Submission type: Initial Study
 Primary contact: Anita Anderson
 IRB coordinator:
 IRB office: KU Lawrence

Entered IRB: 7/8/2013
 Initial approval:
 Effective:
 Approval end:
 Modified: 7/15/2013 9:31 AM

My Current Actions
 Edit Study
 Printer Version
 View Differences

Submit Changes
 Withdraw
 Discard
 Assign Primary Contact
 Manage Guest List
 Copy Submission

History Project Contacts Documents Reviews Snapshots
 Filter by Activity Go Clear Advanced

Activity	Author	Activity Date
Clarification Requested by Designated Reviewer	Dyson Elms, Stephanie Lynn	7/15/2013 9:31 AM CDT
1. Please make changes to the consent form and resubmit revised version. 2. Submit copies of survey. 3. Some additional changes.		
<input checked="" type="checkbox"/> Pre-Review Submitted	Dyson Elms, Stephanie Lynn	7/15/2013 9:28 AM CDT
<input checked="" type="checkbox"/> Submitted	Anderson, Anita	7/8/2013 10:45 AM CDT
<input checked="" type="checkbox"/> Study Created	Anderson, Anita	7/8/2013 10:32 AM CDT

TIP: Use the “Jump” function to skip to certain pages!

Save | Exit | Hide/Show Errors | Print... | **Jump To:** Basic Information ▾

STEP 5: Once you have made the necessary changes, you can exit the study by clicking “Finish” or clicking the “Exit” in the upper gray banner.

Final Page

You have reached the end of the IRB submission form. Read the next steps carefully:

1. Click **Finish** to exit the form.
2. **Important!** To send the submission for review, the principal investigator must click **Submit** on the next page.

<< Back Save | Exit | Hide/Show Errors | Print... | Jump To: Finish

STEP 6: After all required changes have been made, the PI must click the “Submit Changes” button to return the project for further IRB review.

IRB > IRB Submissions > Brand new study

Clarification Requested (Designated Review)

STUDY00000104: Brand new study

Principal investigator: Anita Anderson
Submission type: Initial Study
Primary contact: Anita Anderson
IRB coordinator: Christopher Griffith

IRB office: KU Lawrence

Entered IRB: 8/22/2013
Initial approval:
Effective:
Approval end:
Modified: 9/10/2013 8:30 AM

My Current Actions

- Edit Study
- Printer Version
- View Differences
- Submit Changes**
- Withdraw
- Discard

History | Project Contacts | Documents | Reviews | Snapshots

Filter by: Activity [v] [Go] [Clear] [Advanced]

Activity	Author	
Clarification Requested by Designated Reviewer	Griffith, Christopher Anthony	9
change		
<input checked="" type="checkbox"/> Pre-Review Submitted	Griffith, Christopher Anthony	9
<input type="checkbox"/> IRB Coordinator Assigned	Griffith, Christopher Anthony	9

STEP 7: Provide any clarifications requested in the “Submit Changes” box, but please **do not upload consent forms**. In order for consent documents to be stamped and approved, they need to be resubmitted on the “Consent Form and Recruitment Materials” page. Click OK.

Submit Changes

Notes:

I have made the changes to consent form and have re-uploaded it into the application.
I have uploaded copies of the surveys.

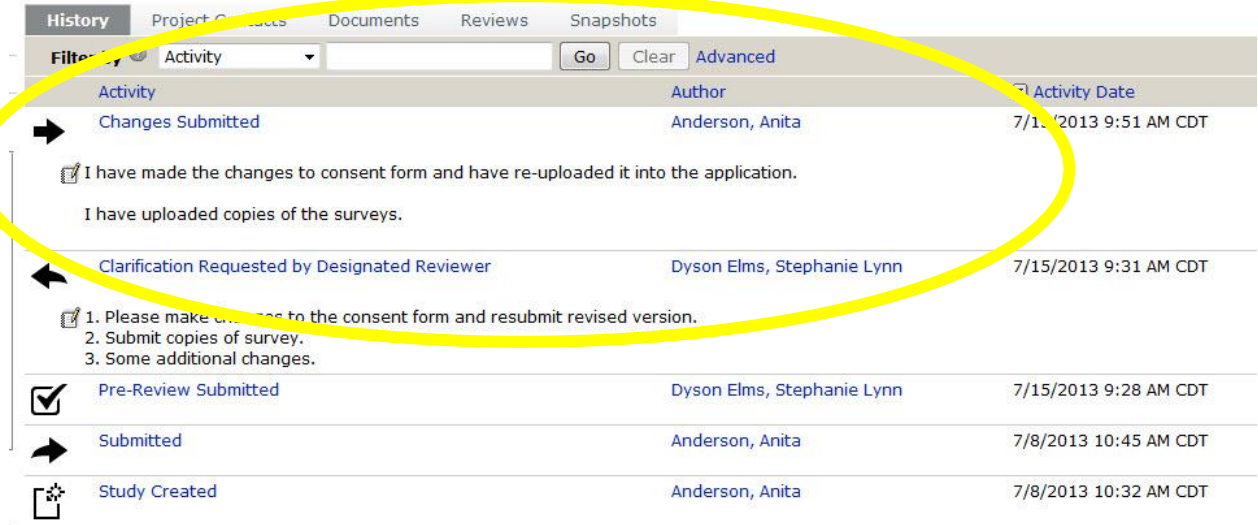
Supporting documents:

Add

Name
There are no items to display

OK Cancel

STEP 8: Your changes will now show up in the “History” and the project will be removed from your inbox. If you have any questions about your project or this process, contact HSCL at hscl@ku.edu.



The screenshot shows the 'History' tab of a web application. A yellow circle highlights the 'Changes Submitted' entry. The table below lists the history items:

Activity	Author	Activity Date
➔ Changes Submitted I have made the changes to consent form and have re-uploaded it into the application. I have uploaded copies of the surveys.	Anderson, Anita	7/15/2013 9:51 AM CDT
➔ Clarification Requested by Designated Reviewer 1. Please make changes to the consent form and resubmit revised version. 2. Submit copies of survey. 3. Some additional changes.	Dyson Elms, Stephanie Lynn	7/15/2013 9:31 AM CDT
☑ Pre-Review Submitted	Dyson Elms, Stephanie Lynn	7/15/2013 9:28 AM CDT
➔ Submitted	Anderson, Anita	7/8/2013 10:45 AM CDT
📄 Study Created	Anderson, Anita	7/8/2013 10:32 AM CDT

Looking for something else? There is more information available on the HSCL website:

Quickstart

- ✓ [Accessing an Approved Study](#)
- ✓ [Creating a Study](#)
- ✓ [Modification and Continuing Review](#)
- ✓ Continuing Review Determination Guide
- ✓ [Closing a Study](#)

Guides

- ✓ [Student/Faculty Supervisor Submission Guide](#)
- ✓ [Study Submission Guide](#)

FAQs

- ✓ [eCompliance FAQs](#)