

Responding to Clarifications in eCompliance

Note: You have 180 days to respond to clarifications. If you do not respond to clarifications within the time permitted, your study will be administratively closed and you will be asked to submit a new study for review.

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 eCompliance system interface. At the top, there is a red navigation bar with 'Home', 'IRB', and 'COI' links. Below this is a grey bar indicating the user is 'Page for Anita Anderson'. The main content area is divided into sections for 'My Current IRB Actions' and 'My Current COI Activities'. The 'My Current IRB Actions' section includes buttons for 'Create New Study' and 'Report New Information'. Below these buttons is a filter section with 'Filter by' set to 'ID' and a search input field. The main part of the interface is a table with the following columns: ID, Name, SmartForm, Date Created, Owner, State, PI First Name, PI Last Name, Date Submitted, and Expiration Date. The first row of the table is highlighted with a yellow circle and contains the following data: ID: STUDY00002333, Name: Study Test 1, SmartForm: [Edit], Date Created: 3/17/2015 11:37 AM, Owner: Ward, Jaimie L, State: Clarification Requested (Designated Review), PI First Name: Anita, PI Last Name: Anderson, Date Submitted: 3/17/2015 11:49 AM, and Expiration Date: (blank).

ID	Name	SmartForm	Date Created	Owner	State	PI First Name	PI Last Name	Date Submitted	Expiration Date
STUDY00002333	Study Test 1	[Edit]	3/17/2015 11:37 AM	Ward, Jaimie L	Clarification Requested (Designated Review)	Anita	Anderson	3/17/2015 11:49 AM	

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.

Home IRB COI

IRB > IRB Submissions > Study Test 1

Clarification Requested (Designated Review)

STUDY00002333 : Study Test 1

Principal investigator: Anita Anderson
 Submission type: Initial Study
 Primary contact: Anita Anderson
 IRB coordinator: Jaimie Ward

IRB office: KU Lawrence

Entered IRB: 3/17/2015 11:49 AM
 Initial approval:
 Effective:
 Approval end:
 Modified: 3/17/2015 11:53 AM

My Current Actions

- Edit Study
- Printer Version
- View Differences
- Submit Response
- Withdraw
- Discard
- Assign Primary Contact
- Manage Guest List
- Copy Submission
- Add Comment
- NotifyPI

History Funding Project Contacts Documents Reviews Snapshots

Filter by Activity

Activity	Author	Activity Date
Clarification Requested by Designated Reviewer	Ward, Jaimie L	3/17/2015 11:53 AM
<ul style="list-style-type: none"> 1. Please make changes to consent form and resubmit revised version. 2. Submit copies of survey. 3. Some additional changes. 		
Pre-Review Submitted	Ward, Jaimie L	3/17/2015 11:51 AM
IRB Coordinator Assigned	Ward, Jaimie L	3/17/2015 11:51 AM
Assigned to Jaimie Ward		
Submitted	Anderson, Anita	3/17/2015 11:49 AM
Study Created	Anderson, Anita	3/17/2015 11:37 AM

STEP 3: The “Edit Study” button allows you to edit the original application and make any changes. Resubmit or add 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

Clarification Requested (Designated Review)

STUDY00002333 : Study Test 1

Principal investigator: Anita Anderson **IRB office:** KU Lawrence

Submission type: Initial Study

Primary contact: Anita Anderson

IRB coordinator: Jaimie Ward

Entered IRB: 3/17/2015 11:49 AM

Initial approval:

Effective:

Approval end:

Modified: 3/17/2015 11:53 AM

My Current ACTIONS

- Edit Study
- View Differences
- Submit Response
- Withdraw
- Discard
- Assign Primary Contact
- Manage Guest List
- Copy Submission
- Add Comment
- NotifyPI

History Funding Project Contacts Documents Reviews Snapshots

Filter by Activity Go Clear Advanced

Activity	Author	Activity Date
Clarification Requested by Designated Reviewer	Ward, Jaimie L	3/17/2015 11:53 AM
1. Please make changes to consent form and resubmit revised version. 2. Submit copies of survey. 3. Some additional changes.		
Pre-Review Submitted	Ward, Jaimie L	3/17/2015 11:51 AM
IRB Coordinator Assigned	Ward, Jaimie L	3/17/2015 11:51 AM
Assigned to Jaimie Ward		
Submitted	Anderson, Anita	3/17/2015 11:49 AM
Study Created	Anderson, Anita	3/17/2015 11:37 AM

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

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

STEP 4: Once you have made the necessary changes, you can exit the study by clicking “Finish” or clicking the “Exit” in the upper gray banner.

Supporting Documents

Attach supporting files, naming them as you want them to appear in the approval letter:

Add

Document	Category	Date Modified	Document History
There are no items to display			

Suggested attachments:

- Completed checklist of meeting Department of Energy requirements, if applicable
- Other study-related documents not attached on previous forms

STEP 5: After all required changes have been made, the PI must click the “Submit Response” button to return the project for further IRB review.

**Clarification Requested
(Designated Review)**

STUDY00002333 : Study Test 1

Principal investigator: Anita Anderson
Submission type: Initial Study
Primary contact: Anita Anderson
IRB coordinator: Jaimie Ward

IRB office: KU Lawrence

Entered IRB: 3/17/2015 11:49 AM
 Initial approval:
 Effective:
 Approval end:
 Modified: 3/17/2015 11:53 AM

My Current Actions

- [Edit Study](#)
- [Printer Version](#)
- [View Differences](#)
- [Submit Response](#)
- [Withdraw](#)
- [Discard](#)
- [Assign Primary Contact](#)

History	Funding	Project Contacts	Documents	Reviews	Snapshots
Filter by Activity <input type="text"/> <input type="button" value="Go"/> <input type="button" value="Clear"/> <input type="button" value="Advanced"/>					
Activity					Author
← Clarification Requested by Designated Reviewer					Ward, Jaimie L
<ul style="list-style-type: none"> 1. Please make changes to consent form and resubmit revised version. 2. Submit copies of survey. 3. Some additional changes. 					
✓ Pre-Review Submitted					Ward, Jaimie L
✓ IRB Coordinator Assigned					Ward, Jaimie L

STEP 6: Provide any clarifications requested in the “Submit Response” 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 Response

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:

Name
There are no items to display

STEP 7: Your changes will now show up in the “History” tab 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.

History	Funding	Project Contacts	Documents	Reviews	Snapshots
Filter by	Activity	Go	Clear	Advanced	
Activity	Author				
 Response Submitted	Anderson, Anita				
 I have made the changes to consent form and have re-uploaded it into the application. I have uploaded copies of the surveys.					
 Clarification Requested by Designated Reviewer	Ward, Jaimie L				
 1. Please make changes to consent form and resubmit revised version. 2. Submit copies of survey. 3. Some additional changes.					
 Pre-Review Submitted	Ward, Jaimie L				
 IRB Coordinator Assigned	Ward, Jaimie L				
 Assigned to Jaimie Ward					
 Submitted	Anderson, Anita				
 Study Created	Anderson, Anita				

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](#)
- ✓ [Closing a Study](#)
- ✓ Student Ancillary Review
- ✓ Faculty Ancillary Review

Guides

- ✓ [Study Submission Guide](#)

FAQs

- ✓ [eCompliance FAQs](#)