

Create a Modification Request in eCompliance

STEP 1: Go to ecompliance.ku.edu and log in using your KU ID and password.

STEP 2: Access the study in the IRB “Active” tab (See Quickstart Guide for Accessing a Study)

STEP 3: Click the “Create Modification/CR” button.

The screenshot displays the eCompliance system interface for a study titled "STUDY00000003: staging test". The interface includes a navigation bar with "Home", "IRB", and "COI" links. Below the navigation bar, the study status is "Approved". The study details include:

- Entered IRB: 6/24/2013
- Initial approval: 6/24/2013
- Effective: 7/5/2013
- Approval end: 7/17/2013
- Modified: 7/8/2013 12:03 AM
- Principal investigator: Anita Anderson
- Submission type: Initial Study
- Primary contact: Nathan Ness
- IRB coordinator: George Garretson
- IRB office: KUMC
- Letter: Correspondence_for_STUDY00000003.pdf(0.02)

A flowchart illustrates the IRB process: Pre-Submission → IRB Pre-Review → IRB Review → Post Review → Review Complete. Each step has a feedback loop for "Clarifications Requested" or "Modifications Required".

On the left, the "My Current Actions" menu is visible, with the "Create Modification / CR" button highlighted in a yellow circle. Other actions include View Study, Printer Version, View Differences, Report New Information, Assign Primary Contact, Manage Guest List, Copy Submission, and Add Comment.

The main content area shows a "History" tab with a filter set to "Activity". The activity log includes:

Activity	Author	Activity Date
Letter Sent	Blackwell, Karen Tiemann	7/5/2013 5:07 PM CDT
Correspondence_for_STUDY00000003.pdf		
Modification MOD00000012 closed (Approved)	Blackwell, Karen Tiemann	7/5/2013 5:03 PM CDT
Modification MOD00000007 closed (Approved)	Blackwell, Karen Tiemann	7/5/2013 3:33 PM CDT
Continuing Review CR00000003 Approved	Blackwell, Karen Tiemann	7/5/2013 3:27 PM CDT
Continuing Review: CR00000003		
Continuing Review Deadline Passed	Administrator	7/4/2013 12:00 AM CDT

STEP 4: Choose “Modification” if you want to change some part(s) of your study.

You can select “Modification and Continuing Review” only if you also need to renew your project for another 12 months (within 30 days of expiration).



You Are Here: [An Approved Study](#) > [Modification #1](#)
for Study STUD...

<< Back Exit | Hide/Show Errors | Print... | Jump To: Modification / Continuing Review Continue >>

Modification / Continuing Review

* What is the purpose of this submission?

- Continuing Review
- Modification**
- Modification and Continuing Review

STEP 5: Next, select the scope of the change (check both boxes if unsure). Click “Continue”.

You Are Here: [_IRBSubmission](#) > [_IRBSubmission](#)
<< Back Save | Print...

Modification / Continuing Review

* What is the purpose of this submission?

- Continuing Review
- Modification
- Modification and Continuing Review**

Modification Scope:

- Study team member informatio
- Other parts of the study

Active modification for this study Modification type(s)

STEP 6: On the Modification Information page you can provide information about the changes you are requesting. Check all boxes that are relevant to your modification.

Use the “Summarize the modifications” section (required) to clearly describe the changes you are requesting.

1. In lay terms, summarize the key changes being proposed.
2. Summarize the reason for the changes.
3. List the documents included in the submission.

It is also helpful to list the names of study personnel you are adding or removing here.

Modification Information

1. Study enrollment status:

- No subjects have been enrolled to date
- Subjects are currently enrolled
- Study is permanently closed to enrollment
- All subjects have completed all study-related interventions
- Collection of private identifiable information is complete

Check only the boxes relevant to your proposed changes

2. Notification of subjects: (check all that apply)

- Current subjects will be notified of these changes
- Former subjects will be notified of these changes

Attach files: If notifying subjects, add a description of how they will be notified to the Supporting Documents page.

3. * Summarize the modifications: ?

Outline your changes here, include the reason for changes, documents associated and list names of study personnel being added or removed

STEP 7: You can now edit the original study, including uploading new documents, and changing the information within eCompliance (PI, study team, funding, etc.).

Also, when revising documents it will reduce review time if you include a clean and marked version so it is easier for the reviewer to see what you have changed within the documents.

Click “Finish” on the last page or “Save” and “Exit” from the menu.

*NOTE: Consent forms **must** be uploaded in the “Consent forms” section on the “Consent Forms and Recruitment Materials” page.*

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.

STEP 8: In order to submit your modification for review by HSCL staff, **click the “Submit” button on the left side of the screen.** If you are not the PI on the project, then the PI will need to log in and click the “Submit” button.

Home IRB COI

IRB > IRB Submissions > Study Test 1

Pre-Submission **STUDY00000043: Study Test 1** **IRB office:** KU Lawrence

Entered IRB: **Principal investigator:** Anita Anderson
Initial approval: **Submission type:** Initial Study
Effective: **Primary contact:** Anita Anderson
Approval end: **IRB coordinator:**
Modified: 7/8/2013 10:37 AM

Pre-Submission → IRB Pre-Review → IRB Review → Post Review → Review Complete
Clarifications Requested (between IRB Pre-Review and IRB Review)
Clarifications Requested (between IRB Review and Post Review)
Modifications Required (between Post Review and Review Complete)

My Current Actions

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

History Project Contacts Documents Reviews Snapshots

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

Activity	Author	Activity Date
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

- ✓ Creating a Study
- ✓ Continuing Review
- ✓ Responding to Clarifications
- ✓ Closing a Study

Guides

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

FAQs

- ✓ [eCompliance FAQs](#)