

Creating a Study Team Modification 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 shows the eCompliance system interface for a study titled "STUDY00000003: staging test". The top navigation bar includes "Home", "IRB", and "COI". The breadcrumb trail is "IRB > IRB Submissions > staging test".

Approved

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

STUDY00000003: staging test

Principal investigator: Anita Anderson
Submission type: Initial Study
Primary contact: Nathan Ness
IRB coordinator: George Garretson

IRB office: KUMC
Letter: [Correspondence_for_STUDY00000003.pdf\(0.02\)](#)

The workflow diagram shows the following steps: Pre-Submission → IRB Pre-Review → IRB Review → Post Review → Review Complete. There are feedback loops for "Clarifications Requested" between IRB Pre-Review and IRB Review, and between IRB Review and Post Review. There is also a "Modifications Required" loop between Post Review and Review Complete.

My Current Actions

- View Study
- Printer Version
- View Differences
- Create Modification / CR** (highlighted in yellow)
- Request New Information
- Assign Primary Contact
- Manage Guest List
- Copy Submission
- Add Comment

History | Project Contacts | Documents | Follow-on Submissions | Reviews | Snapshots

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


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 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).

<< Back Save | | Print...

Modification / Continuing Review / Study Closure

* What is the purpose of this submission? 

- Continuing Review
 - Modification 
 - Modification and Continuing Review
- [Clear](#)

STEP 5: For the scope of the study, select “Study team member information” to add or remove a study team member. Click “Continue”.

Modification scope:

- Study team member information
- Other parts of the study

Active Modification for This Study

Modification Type

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:

List names of study personnel being added or removed

STEP 7: You can now add or remove a person from your study team. Click “Finish” when you are done making changes.

****Note:** Only current faculty/staff/graduate students will show up in this list. Undergraduates may not show up in this list. If you need an undergraduate added to eCompliance, please contact HSCL by telephone with their 7-digit KU ID (785-864-7429), or send an encrypted email to hscl@ku.edu. If you have an external study team member for your study, please contact hscl@ku.edu for additional information on adding external members to your study.

Study Team Members

1. Identify each additional person involved in the design, conduct, or reporting of the research: 

Name	Roles	Financial Interest	Involved in Consent	E-mail	Phone
There are no items to display					

<< Back
Save | Exit | Hide/Show Errors | Print... | Jump To: Study Team Members ▾
Finish

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.

Pre-Submission

MOD00007023 : Modification #5 for Study STUDY00003032

Entered IRB:
Approval:
Effective:
Modified: 9/22/2015 11:09 AM

Investigator: Anita Anderson
Submission type: Modification
Primary contact: Anita Anderson
IRB coordinator:

IRB: KU Lawrence
Letter: None



My Current Actions

- Edit Modification / CR
- Printer Version
- View Differences

- Submit**
- Discard
- Manage Ancillary Reviews
- Add Comment
- NotifyPI

History | Project Contacts | Documents | Related RNIs

Filter by [Advanced](#)

No data to display.

Looking for something else? There is more information available on the HSCCL 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](#)