

Modification and/or Continuing Review 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 4: Click the “Create Modification/CR” button.

The screenshot shows the eCompliance interface for 'STUDY00000003: staging test'. The 'My Current Actions' sidebar on the left contains several buttons, with 'Create Modification / CR' highlighted by a yellow circle. The main content area displays a workflow diagram and a history table.

Workflow Diagram:

```

    graph LR
      A[Pre-Submission] --> B[IRB Pre-Review]
      B --> C[IRB Review]
      C --> D[Post Review]
      D --> E[Review Complete]
      B --> B1[Clarifications Requested]
      B1 --> B
      C --> C1[Clarifications Requested]
      C1 --> C
      D --> D1[Modifications Required]
      D1 --> D
  
```

History Table:

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 5: Determine if you are requesting Continuing Review, Modification or **both**.

The screenshot shows the 'Modification / Continuing Review' section of the eCompliance system. The 'You Are Here' breadcrumb trail indicates the user is viewing 'An Approved Study' > 'Modification #1'. The 'Jump To' dropdown menu is set to 'Modification / Continuing Review'.

Modification / Continuing Review

- * What is the purpose of this submission?
- Continuing Review
 - Modification**
 - Modification and Continuing Review

NOTE: “Continuing Review” is a new term for “Status Report” and “Modification” is the new word for “Amendment.”

CR/MOD Determination Help

CR CLOSURE: To close a study, select “Continuing Review”

CR/MOD: Choose “Modification and Continuing Review” if you have received a Continuing Review notification and you also want to modify your study.

MOD: To make changes to a study at any time, select “Modification”.

CR: Select “Continuing Review” if you have received a Continuing Review notification, have no changes and your study is closed to new or continuing enrollment.

CR/MOD (TRANSITION): Select “Modification and Continuing Review” if you have received a Continuing Review notification and your study is open for new or continuing enrollment. *This option may apply to projects that were approved before June 17, 2013.*

*NOTE: Consent forms were **not** uploaded when the system launched. Consent forms will need to be uploaded when you complete the Continuing Review/Modification (Transition) on the “Consent Forms and Recruitment Materials” page for projects that were originally approved before eCompliance launched.*

STEP 6: If requesting a Modification or Modification/Continuing Review, select the scope of the change.

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

[Clear](#)

Modification Scope:

- Study team member information
- Other parts of the study

Active modification for this study Modification type(s)

STEP 7: Continue through the pages and upload any necessary documents. You will have the opportunity to edit your entire study when the Modification Scope includes “Other Parts of the Study.” Click “Finish.”

*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 study 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 **STUDY0000043: 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

Flowchart: Pre-Submission → IRB Pre-Review → IRB Review → Post Review → Review Complete. Loops: IRB Pre-Review ↔ Clarifications Requested; IRB Review ↔ Clarifications Requested; Post Review ↔ Modifications Required.

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

*NOTE: Once you have submitted your study, you can check on the progress of your submission by logging in and viewing the **status bar**.*

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

Quickstart

- ✓ 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](#)