

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

Home IRB COI

IRB > IRB Submissions > staging test

Approved

STUDY00000003: staging test

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)

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

- View Study
- Printer Version
- View Differences
- Create Modification / CR**
- Assign Primary Contact
- Manage Guest List
- Copy Submission
- Add Comment

History Project Contacts Documents Follow-on Submissions Reviews Snapshots


Filter by Activity 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 “Continuing Review” or “Modification and Continuing Review.”

Choose “Continuing Review” only when **no** changes need to be made to the study. Choose combination “MOD/CR” when you need to make changes **and** want to renew the study for another 12 months.

Modification / Continuing Review / Study Closure

* What is the purpose of this submission? 

- Continuing Review
- Modification
- Modification and Continuing Review

STEP 5: If requesting a Modification/Continuing Review, select the scope of the change, then click “Continue.”

Modification / Continuing Review

* What is the purpose of this submission?

- Continuing Review
- Modification
- Modification and Continuing Review

Modification Scope:

- Study team member information
- Other parts of the study

Accept modification for this study: _____ Modification type(s) _____



Continue >>

STEP 6: Complete the Continuing Review/Study Closure

STEP 6a. Indicate how many people have participated in your study.

Continuing Review / Study Closure Information

1. * Specify enrollment totals:

	Subjects Enrolled	Total	Since Last Approval
At this investigator's sites:		<input type="text" value="398"/>	<input type="text" value="398"/>
Study-wide:		<input type="text" value="988"/>	

STEP 6b. Check only the research milestones that apply to this specific study. If none apply, you are not required to check any boxes.

Research milestones: (select all that apply)

- Study is permanently closed to enrollment
- All subjects have completed all study-related interventions
- Collection of private identifiable information is complete
- Analysis of private identifiable information is complete
- Remaining study activities are limited to data analysis
- Study remains active only for long-term follow-up of subjects

STEP 6c. Indicate if any study team members, including the PI, have any previously undisclosed financial conflicts of interest.

Do any investigators or research staff have a financial interest related to the research that was not described in a previous application?

Yes No [Clear](#)

STEP 6d. The next section helps the IRB determine if the risks and/or benefits have changed since you originally submitted the study. In most cases, all the boxes should be checked to confirm that the statement is TRUE.

Check the items that are true since the last IRB continuing review for all sites involved in the study:

- NO subjects experienced harm (expected or unexpected)
- NO subjects experienced benefit
- NO subjects withdrew from the study
- NO unanticipated problems involving risks to subjects or others
- NO complaints about the study
- NO publications in the literature relevant to risks or potential benefits
- NO interim findings
- NO multi-center trial reports
- NO data safety monitoring reports
- NO regulatory actions that could affect safety and risk assessments
- NO other relevant information regarding this study, especially information about risks
- In the opinion of the PI, the risks and potential benefits are unchanged
- All modifications to the protocol have been submitted to the IRB
- All problems that require prompt reporting to the IRB have been submitted

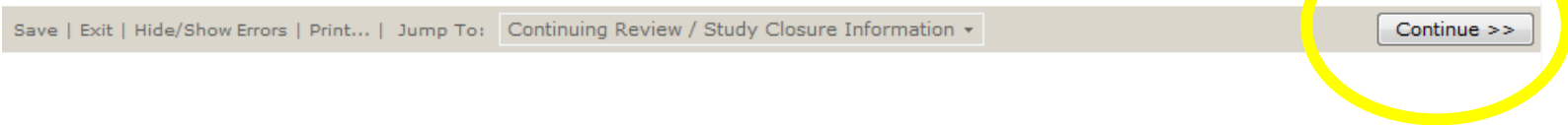
STEP 6e. If any boxes were left unchecked, submit a document that explains why. Do NOT upload consent forms or any other study related materials here.

Attach supporting documents: (include an explanation of each item left unchecked above)

Name

There are no items to display

STEP 7: Click the “Continue” button. (If Modification and Continuing Review was selected, you will now be able to complete your modification request.)



STEP 8: Click the “Finish” button.



STEP 9: In order to submit your continuing review for evaluation 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.

A screenshot of the IRB submission interface. At the top, there is a red navigation bar with 'Home IRB COI' and a breadcrumb trail 'IRB > IRB Submissions > Study Test 1'. The main heading is 'STUDY0000043: Study Test 1' with 'Pre-Submission' highlighted. Metadata includes 'Entered IRB:', 'Initial approval:', 'Effective:', 'Approval end:', 'Modified: 7/8/2013 10:37 AM', 'Principal investigator: Anita Anderson', 'Submission type: Initial Study', 'Primary contact: Anita Anderson', 'IRB coordinator:', and 'IRB office: KU Lawrence'. A process flow diagram shows steps: Pre-Submission, IRB Pre-Review (with Clarifications Requested), IRB Review (with Clarifications Requested), Post Review (with Modifications Required), and Review Complete. On the left, 'My Current Actions' includes buttons for 'Edit Study', 'Printer Version', 'View Differences', and 'Submit' (circled in red), along with 'Discard', 'Assign Primary Contact', 'Manage Guest List', 'Copy Submission', and 'Add Comment'. A 'History' table is visible with columns for Activity, Author, and Activity Date. The first entry is 'Study Created' by 'Anderson, Anita' on '7/8/2013 10:32 AM CDT'.

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](#)