

Creating a Continuing Review in eCompliance

1. Go to ecompliance.ku.edu and log in using your KU ID and password.
2. Access the study in the IRB by clicking the “IRB” link in the red banner, and clicking the “All Submissions” tab. (See Guide for [Accessing a Study](#))
3. Click the “Create Modification/CR” button.

Approved

STUDY00141151

Study Test

Principal investigator: Anita Anderson
Submission type: Initial Study
Primary contact: Anita Anderson
IRB coordinator: Caitlin Carter

IRB office: KU Lawrence
Letter: Correspondence_for_STU

Entered IRB: 7/26/2017 1:37 PM
Initial approval: 7/26/2017
Initial effective: 7/26/2017
Effective: 7/26/2017
Approval end: 7/29/2017
Last updated: 7/26/2017 1:39 PM

Next Steps

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

History | Funding | Project Contacts | Documents | Follow-on Submissions | Review

Filter: Activity [v] Enter text to search for [] Go + Add Filter x Clear All

Activity	Author	Activit
Letter Sent	Carter, Caitlin Diane	7/26/201
Correspondence_for_STUDY00141151.pdf		
Pre-Review Submitted	Carter, Caitlin Diane	7/26/201
IRB Coordinator Assigned	Carter, Caitlin Diane	7/26/201
Assigned to Caitlin Carter		
Submitted	Anderson, Anita	7/26/201

4. Choose “Continuing Review”

Modification / Continuing Review / Study Closure

* What is the purpose of this submission? ?

- Continuing Review
- Modification and Continuing Review
- Modification/Update

5. Complete the Continuing Review Information page

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

At this investigator's sites: For multi-site studies, add only the number participants for KU. If only KU is participating in this project, this number will be the same as your "Study-Wide" total.

Study Wide: For multi-site studies, add the total number of participants across all sites. If research is only taking place at KU, this number will be the same as the "Investigator sites" total.

Since Last approval: Amount of people who have participated since your last Continuing Review (CR) was submitted. If this is your first CR, this number will be the same as your "Study-Wide" total.

Continuing Review / Study Closure Information

1. * Specify enrollment totals:

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

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

2. Research milestones: (select all that apply) ?

- Study is permanently closed to enrollment OR was never open for enrollment
- All subjects have completed all study-related interventions OR not applicable (e.g. study did not include interventions, no subjects were enrolled)
- Collection of private identifiable information is complete OR not applicable (no subjects were enrolled)
- Analysis of private identifiable information is complete OR not applicable (no subjects were enrolled)
- Remaining study activities are limited to data analysis
- Study remains active only for long-term follow-up of subjects

i Important! If the first four research milestones above are complete, the study will be closed to discontinue IRB oversight.

STEP 6c. Indicate if any study team members, including the PI, have any financial interests related to this study.

3. * 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 statements are TRUE.

4. Check the items that are true since the last IRB approval for all sites involved in the study: (initial review or last continuing review)

- NO subjects experienced unexpected harm
- Anticipated adverse events have NOT taken place with greater frequency or severity than expected
- 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.

5. Attach supporting documents: (include an explanation of each item left unchecked above. If you are submitting to the KUMC or KUSM-W IRB, please also attach your completed Continuing Review Supplement. The form is posted on the IRB website) 

+ Add

Name

There are no items to display

7. Click the "Continue" button.



8. Click the "Finish" button.



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.

Pre-Submission

Entered IRB:
Last updated: 7/14/2017 11:55 AM

Next Steps

- Edit Modification/CR
- Printer Version
- Submit**
- Discard
- Manage Ancillary Reviews
- Add Comment
- NotifyPI

Status Change Alert

DRAFT SUBMISSION STAGE. Click "Submit" or "Notify PI" to send to IRB for review.

CR00005311: Continuing Review for Study STUDY00141109

Principal investigator: Anita Anderson
Submission type: Continuing Review
Primary contact: Anita Anderson
IRB coordinator:

IRB office: KU Lawrence

- Once the study is submitted, the flowchart will change from “Pre-Submission” to “Pre-Review” and the History Activity will show that the study has been “Submitted”. There will also be a green banner at the top of your screen for a few seconds to show submission.

Pre-Review

Entered IRB: 7/26/2017 2:31 PM
Last updated: 7/26/2017 2:31 PM

Next Steps

- View Modification/CR
- Printer Version
- Withdraw
- Discard
- Add Comment

(IRB - Mod/CR - In-Review)

Status Change Alert

Success! Your submission has been sent to the IRB.

CR00005312: Continuing Review for Study STUDY00141151

Principal investigator: Anita Anderson
Submission type: Continuing Review
Primary contact: Anita Anderson
IRB coordinator:

IRB office: KU Lawrence

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

History	Project Contacts	Documents	Related RNIs	Snapshots
Filter ? Activity <input type="text" value="Enter text to search for"/> <input type="button" value="Go"/> <input type="button" value="+ Add Filter"/> <input type="button" value="x Clear All"/>				
Activity	Author	Activity Date		
Submitted	Anderson, Anita	7/26/2017 2:31 PM		

Looking for something else? There is more information available on the [HRPP website](#):

Quickstart

- ✓ [Creating a Study](#)
- ✓ [Modification](#)
- ✓ [Study Team Modification](#)
- ✓ [Accessing a Study](#)
- ✓ [Changing a Principle Investigator](#)
- ✓ [Adding Funding](#)
- ✓ [Creating an External IRB Study](#)
- ✓ [Responding to Clarifications](#)
- ✓ [Closing a Study](#)

Guides

- ✓ [Student Ancillary Review Guide](#)
- ✓ [Faculty Supervisor Ancillary Review Guide](#)