University of Kansas Medical Center - Human Subjects Committee

Create a Continuing Review in eCompliance

**STEP 1:** Go to [ecompliance.ku.edu](http://ecompliance.ku.edu) and log in using your KUMC ID and password.

**STEP 2:** Access the study in the IRB “Active” tab

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

**STEP 4:** Choose “Continuing Review” or “Modification and Continuing Review.” Choose “Continuing Review” when you want to renew the study without changes. Choose combination “MOD/CR” when you want to renew the study and make changes to the study.
STEP 5: If requesting a Modification/Continuing Review, select the scope of the change, then click “Continue.”

STEP 6: Complete the Continuing Review/Study Closure

STEP 6a. Indicate how many people have participated in your study. Reference Section V of the Continuing Review Supplement form for assistance in calculating enrollment totals.

You may also return to the original study page, click on the “Follow-on Submissions” tab, select last year’s Continuing Review item, and navigate to its Continuing Review/Study Closure page to see what was reported during the last period. If there is a discrepancy in the numbers reported between the current continuing review and the previous continuing review, include a comment in the system to explain this.
STEP 6b. Check only the research milestones that apply to this specific study. If none apply, you are not required to check any boxes. This section helps IRB staff determine whether the study requires expedited or full committee review. Note that selecting the first four research milestones will prompt IRB staff to close the study.

**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 any issues have arisen since the last review period. For each statement that is TRUE, check the box for that item. If applicable, provide an explanation for the unchecked items. You may use the Additional Information section of the Continuing Review Supplement form for explanation of unchecked items.

4. 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. Upload your completed Continuing Review Supplement form. Also upload any applicable safety monitoring reports and CRIS AE reports as directed by the Continuing Review Supplement form. Do NOT upload consent forms here.

STEP 7: Click the “Continue” button. (If Modification and Continuing Review was selected, you will now be able to complete your modification request. If you are not making any changes, skip to STEP 10.)

STEP 8: On the Modification Information page you can provide information about any 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 reasons for the changes.
3. List the documents included in the modification submission.

It is also helpful to list the names of study personnel you are adding or removing here.
STEP 9: You can now edit the original study, including uploading new documents, and changing the information within eCompliance (PI, study team, funding, etc.).

Choose the ADD button to add new documents that were not previously submitted. Choose the UPDATE button to submit revised versions of your documents.

Please ensure that any revised documents are in track-changes mode or otherwise highlighted so that changes are clear.

STEP 10: Click the “Finish” button.

Click “Finish” on the last page or “Save” and “Exit” from the banner menu.
STEP 11: In order to submit your Continuing Review/Modification for evaluation, **the PI needs to click the “Submit” button on the left side of the screen.** If you are not the PI on the project, then you may click “Notify PI” to prompt the PI to log in and click the “Submit” button.

Please contact the IRB office with any questions!

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