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.

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 5a. 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:**

<table>
<thead>
<tr>
<th>Subjects Enrolled</th>
<th>Total</th>
<th>Since Last Approval</th>
</tr>
</thead>
<tbody>
<tr>
<td>At this investigator’s sites:</td>
<td>![Image]</td>
<td>![Image]</td>
</tr>
<tr>
<td>Study-wide:</td>
<td>![Image]</td>
<td>![Image]</td>
</tr>
</tbody>
</table>

**STEP 5b. 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

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

**STEP 5c. 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 5d. 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 5e. 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 KU-MA IRB, please also attach your completed Continuing Review Supplement. The form is posted on the IRB website)

Name

There are no items to display
6. Click the “Continue” button.

7. Click the “Finish” button.

8. 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.
9. 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.
Looking for something else? There is more information available on the HRPP website:

Quickstart

✓ Creating a Single-Site Study
✓ Creating a Multi-Site 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