Creating a Modification Request in eCompliance

1. Go to [ecompliance.ku.edu](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 Quickstart Guide for Accessing a Study)

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

4. Choose “Modification” if you want to change some part(s) of your study.
Modification / Continuing Review / Study Closure

* What is the purpose of this submission? ?

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

5. Next, select the scope of the change. Click “Continue”.

**Other Parts of the study:** Check to edit study documents; change study procedures; add external sites; add funding source (see Add Funding Source Guide)

**Study team member information:** Check if you wish to add/delete study team members. See Study Team Modification Guide.

**Note:** If you are trying to change the PI, please use our Change the PI Guide.

6. On the Modification Information page you can provide information about the 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, provide a point-by-point explanation of all of the changes to your study.
2. Summarize the reasons for the changes.
3. Explain if the changes will increase/decrease risks to research participants.
4. Explain how/if participants will be notified of the changes to your study procedures.
5. List the documents included in the submission.
It is also helpful to list the names of study personnel you are adding or removing here.

**Modification Information**

1. **Study enrollment status:**
   - [ ] No subjects have been enrolled to date
   - [ ] Subjects are currently enrolled
   - [ ] Study is permanently closed to enrollment
   - [ ] All subjects have completed all study-related interventions
   - [ ] Collection of private identifiable information is complete

2. **Notification of subjects:** (check all that apply)
   - [ ] Current subjects will be notified of these changes
   - [ ] Former subjects will be notified of these changes

3. **Summarize the modifications:**
   - [ ] Attach files: If notifying subjects, add a description of how they will be notified to the Supporting Documents page.
   - Outline your changes here, include the reason for changes, risks, documents associated and list names of study personnel being added or removed

7. If you clicked the “Other Parts of the Study” and “Study Team Member Scope” scope, you can now edit the original local site documents and upload new documents, edit study team members, add funding sources, etc. If your study is a multi-site study, you will also have the option to edit and add study related documents.

To reduce IRB review time, upload both a tracked changes version and a clean version of any edited documents.

Click “Finish” on the last page or “Save” and “Exit” from the menu.

**NOTE:** Consent forms must be uploaded in the “Consent forms” section on the “Consent Forms and Recruitment Materials” page.
8. In order to submit your modification for review by IRB 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

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✓ Creating a Multi-Site Study
✓ Continuing Review
✓ Accessing a Study
✓ Study Team Modification
✓ Changing 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