

Quick Start / Reference Sheet

For Investigators with Existing Approved Studies:

Submitting Modifications – Other Parts of the Study (NOT Personnel)

Required first step: establish your study in the electronic system. If you have NOT uploaded your current IRB-approved documents to eCompliance, you won't be able to make any changes to your study. See [Uploading your Study Documents into eCompliance for IRB](#) if you have not registered your study in the electronic system.

Accessing the System and Logging In

1. The KUMC eCompliance system can be accessed at <https://ecompliance.ku.edu> or from the KUSM-W Research Compliance [home page](#).
2. Log in using your KUMC Online ID and password.

To View Existing Studies

1. In **My Inbox**, you'll see the IRB and COI tabs. These are tasks under the respective tabs are waiting for your action. To view all your studies, click on "IRB" on the **RED BAR** at the top left.
2. Choose the **Active** tab for a list of your existing studies.
3. Click on the title of the study to which you will be making modifications. This action takes you to the **Study Workspace**, with the title, investigator, submission type and primary contact listed.

To Submit Modifications for amending Other Parts of the Study, excluding changes to personnel list

1. Hit the **Create Modification / CR** button on the left panel under **My Current Actions**.
2. **Modification / Continuing Review screen:** Check **Modification** and **check other parts of the study** under **Modification Scope**. Click **continue** at the top or bottom right side of the screen to move through the screens.
3. **Modification Information:** Question 3 – Describe the proposed changes and rationale for those changes in detail.
4. **Basic Information:** Review Questions 1-7 for accuracy. If proposing changes to the protocol on Question 8, **UPDATE** the current IRB approved protocol with a clean copy of the new version. **ADD** a tracked changes version.
5. **Funding Sources:** if applicable, **ADD** the organization's name from the pre-populated list of sources and any additional info.
6. **Study Scope:** Review Questions 1-3. If changing any scope, review the following:
 - a. If yes on **External Sites**, complete the information about that site.
 - b. If yes on **Drugs**, Answer Question 1 for each FDA approved drug in the hospital formulary and Q. 2 for each investigational drug, attaching product information for each. Question 3 is optional for other attachments.
 - c. If yes on **Devices**, answer Questions 1-2 for each device; attach device manual. Questions 3-4 if applicable.
7. **Consent Form and Recruitment Materials:**
 - a. **UPDATE** "clean" version of consent forms with the clean proposed forms with no footer.
 - b. **ADD** "tracked changes" version if there is not an old tracked changes version listed **OR UPDATE** "tracked changes" version if an old version is listed.
8. **Internal Reporting:** Shouldn't require updating for a modification
9. **Supporting Documents:** Upload new additional items as listed on the [Checklist of Documents to Prepare](#). Click **Finish**.
10. If you are not the PI, click the **Notify PI** button back on the Study Workspace screen. You can add a message or comment to the PI on the pop-up screen. If you are the PI, click **Submit** from **My Current Actions** list on the left.

1