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](https://ecompliance.ku.edu) or from the HRPP home page under [Electronic IRB Submission](#).
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.

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