Quick Start / Reference Sheet

For Investigators with Existing Approved Studies:

Submitting Modifications - Update Study Personnel List AND Other Parts of the Study

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 Changing Study Personnel AND Modifying Other Parts of the Study

1. Hit the **Create Modification / CR** button on the left panel under **My Current Actions.**
2. **Modification / Continuing Review screen:** Check **Modification** and *check both* **study team member** and **other parts of the study** under **Modification Scope.** Click **continue** at the top or bottom right side of 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 Team Members:** Ensure that all study personnel are listed. **ADD** any missing name from the pre-populated list and indicate his/her role, involvement in the consent process, and any related financial interest. Click **OK and Add Another** if multiple personnel need to be added. Click **OK** upon completion of the list.
7. **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.
8. **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.
9. **Internal Reporting:** Shouldn't require updating for a modification.
10. **Supporting Documents:** Upload new additional items as listed on the Checklist of Documents to Prepare. Click **Finish**.
11. 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.