Quick Start / Reference Sheet
For Investigators with Existing Approved Studies:
Uploading your Study Documents into eCompliance for IRB

**Required first step** to establish your study in the electronic system: Follow the actions outlined below to upload current IRB-approved documents before making any subsequent changes to your study.

### 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 OR Assign your Study Coordinator

1. In **My Inbox**, you’ll see the IRB and COI tabs. These are tasks under the respective tabs that 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 uploading documents. This action takes you to the **Study Workspace**, with the title, investigator, submission type and primary contact listed. The yellow status bar in the upper left hand corner will indicate that it was **Approved** prior to the launch of eCompliance.
4. A framework of each current approved study was uploaded in early July, consisting of title, existing HSC number, PI name, and expiration date. The study documents (IRB protocol, Drug or device descriptions, Investigator’s brochure, and / or all consent forms) must be uploaded by the study PI OR by an assigned primary contact i.e., Research Institute or Cancer Center personnel, study coordinator. To have your study coordinator upload the documents for your submission, click on **Assign Primary Contact** and select the person’s name from the drop down list; click **OK**. For most studies the primary contact will be pre-populated.

### To Upload Documents for Existing Approved Studies that are NOT due for Continuing Review

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 boxes** under **Modification Scope** (study team member, other parts of the study). Click **continue** at the top or bottom right side of the screen to move through the screens.
3. **Modification Information**: Question 3 = “initial upload of current documents for existing study”
4. **Basic Information**: Complete Questions 1-7. On Question 8, ADD the current IRB approved protocol.
5. **Funding Sources**: 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**: Answer Questions 1-3
   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, attaching device manual. Questions 3-4 if applicable.
8. **Consent Form and Recruitment Materials**: ADD all current IRB approved consent forms in Word only with no footer, for approval stamp in the system. Approved recruitment materials are not required at this time.
9. **Internal Reporting**: Categorize your study to allow for new institutional reporting.
10. **Supporting Documents**: Not required for this initial upload of approved studies. 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.
To Upload Documents for Existing Approved Studies that are DUE for Continuing Review

1. Hit the Create Modification / CR button on the left panel under My Current Actions.
2. Modification / Continuing Review screen: Check Modification and Continuing Review and check both boxes under Modification Scope (study team member, other parts of the study). Click continue at the top or bottom right side of the screen to move through the screens.

4. Modification Information: Question 3 = “initial upload of current documents for existing study.” FOR THE PURPOSE OF THIS INITIAL UPLOAD: Please do not make any changes to your current study at this time. You will be able to create a modification after this initial upload of your existing documents has been processed by HSC staff.
5. Basic Information: Complete Questions 1-7. On Question 8, ADD the current IRB approved protocol.
6. Funding Sources: ADD the organization’s name from the pre-populated list of sources and any additional info
7. 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.
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