Quick Start / Reference Sheet
For Investigators who have a Continuing Review AND Need to Register Existing Approved Studies in the new eIRB system:
Continuing Review AND Uploading your Study Documents

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

Accessing the System and Logging In

1. The KUMC eIRB system can be accessed at 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. Logging in will take you to your Inbox.
2. To view all your studies, click on “IRB” on the RED BAR at the top left.
3. Choose the Active tab for a list of your existing studies.
4. 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 eIRB.
5. A framework of each current approved study was uploaded in early July, consisting of title, existing HSC number, PI name, expiration date. If you do NOT see your study, contact HSC office 8-1240.

To Upload Documents for Existing Approved Studies 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 AND other parts of the study). Click continue at the top or bottom right side of the screen to move through the screens.
3. Continuing Review / Study Closure Information: Answer Questions 1-4. On item 4, only check the items that are true. If adverse events have occurred, ensure that they have been previously reported if required.
   a. Upload your completed Continuing Review Supplement for Question 5 (Required). The Supplement is found on our Forms web page.
   b. The initial upload of your approved documents into eIRB is classified as a “modification” by the system. Hit Continue to proceed with the questions related to Modification.
4. Modification Information: Please answer Question 3 as “initial upload of current documents for existing study.”
   a. 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.
   b. Please consult with the HSC Office if you need to make a protocol amendment at the same time you are filing the Continuing Review.
   c. Hit Continue to proceed to the individual tabs where you will “flesh out” the limited information that was pre-populated.
5. Basic Information: Complete Questions 1-7. On Question 8, upload the required current IRB approved protocol from your desktop by clicking on ADD.
6. **Funding Sources:** Confirm that the correct sponsor has been pre-populated. If not, **ADD** the organization’s name from the pre-populated list of sources and any additional info. Contact the HSC Office if your sponsor is not listed in the drop-down box.

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. Contact the HSC Office if you need to add an individual who is not listed.

8. **Study Scope:** Answer Questions 1-3. Affirmative answers will generate additional questions.
   a. If you have indicated that the KUMC PI is responsible for **External Sites**, complete the information about that site.
   b. If you have indicated that the study involves **Drugs**, each drug used in the study must be **listed individually**. Use Question 1 if the drug is FDA-approved drug and in the hospital formulary. Use Question 2 for each investigational drug, indicating the IND number and attaching the Investigators Brochure for each. Question 3 is optional for other attachments.
   c. If you have indicated the study involves **Devices**, answer Questions 1-2 for each device, attaching device manual. Questions 3-4 if applicable.

9. **Consent Form and Recruitment Materials:** Upload all current **IRB approved** consent forms in **Word only with no footer and no page numbers**, by clicking **ADD**. This will allow the system to stamp the renewed consent form after continuing review is complete. Previously-approved recruitment materials are not required at this time.

10. **Internal Reporting:** Categorize your study to allow for new institutional reporting.

11. **Supporting Documents:** Not required for this initial upload of approved studies. Click **Finish**.

12. 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.