Quick Start / Reference Sheet

for Investigators, Regulatory Staff, or Study Coordinators:

Creating and Submitting New Studies in eCompliance for IRB

Accessing the System and Logging In

1. The KUMC eCompliance system can be accessed at http://ecompliance.ku.edu or from the Research Compliance home page.
2. Log in using your KUMC user name and password.

Before you begin: Gather your Documents

1. A checklist of documents to prepare for submission can be found on the next page of this guide.

To Create a New Study

1. From **My Inbox**, click **Create New Study.**
2. **Basic Information:** Answer Questions 1-7. On Question 8, **ADD** the proposed study protocol.
3. **Funding Sources: ADD** the organization's name from the pre-populated list of sources and any additional info
4. **Study Team Members:** Ensure that all study personnel are listed. 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.
5. **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 drug being used in the study. Answer Q. 2 for each investigational drug. 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.
6. **Consent Form and Recruitment Materials:** See Checklist of documents on next page.
7. **Internal Reporting:** Categorize your study to allow for new institutional reporting.
8. **Supporting Documents:**
    a. Project Description required for selected review.
    b. Signed Scientific Merit/Department Chair Review form, unless these reviews will be completed electronically as Ancillary Reviews.
    c. Other supporting documents. Click **Finish**.
9. **Manage Ancillary Reviews:** To electronically submit the Scientific Merit Review and Department Chair Review, click the **Manage Ancillary Reviews** button on the Study Workspace screen. Click **ADD** then complete the 3 questions in the new window that opens:
    a. Enter the **Reviewing Person**'s name who is responsible for completing the selected review.
    b. Specify **Review Type** from the dropdown box.
    c. **Is a response required?** Select "Yes" as both the Scientific and Department Reviews are required for all Full Committee and Expedited reviews. Click **OK and Add Another** if multiple reviews need to be added. Click **OK** once the Scientific Review and Department Review have been added. Once the PI submits the study, the Scientific/Department reviewer will receive an email notification instructing him/her to complete the review.

To Submit an Ancillary Review (Scientific or Department Review):

i. The reviewer will login to eCompliance and navigate to the study workspace.
ii. Click the **Submit Ancillary Review** button on the left side of the screen. Answer Questions 1-2. Provide comments if applicable. If completing the Scientific Review, upload the completed Scientific Merit Checklist to the "Supporting Documents" section. Click **OK** to submit the review.

To Submit a New Study

1. 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.
2. If you are the PI, review the screens or the Printer Version of the study. When you are satisfied with the entire application including uploaded documents, click **Submit** from **My Current Actions** list on the left.

Checklist of Documents for Human Subjects Committee Application in eIRB	
eIRB Screen	**Documents to Prepare and Upload**
Basic Information	*Proposed study protocol
Funding Sources	Grant applications (if applicable)
Study Team Members	N/A
Study Scope	N/A
External Sites (if checked in Study Scope)	Letter of support (if applicable). Upload in Supporting Documents section.
Drugs (if checked in Study Scope)	For investigational drugs: Investigator's brochure, FDA letters (if applicable)
Devices (if checked in Study Scope)	Device Manual
Consent Form and Recruitment Materials	All proposed consent forms in Word only with no footer. All proposed recruitment materials
Internal Reporting	N/A
Supporting Documents	*Project Description for Full Committee Review, Exempt, Expedited, or Retrospective Studies If Applicable: • Signed Scientific Merit/Dept Chair Review • Surveys, instruments • Data collection sheet • DSMB or DMC Charter • Subject instructions, diaries, etc. • PRMC approval letter • Sponsor correspondence • HIPAA waiver request
	***Required on all new studies**