Quick Start / Reference Sheet

Answering Provisos in eCompliance

Notification and Accessing the System

1. The eCompliance system will send a notification to investigators when the convened IRB or designated reviewer (for exempt and expedited studies) requires changes to the study prior to approval.
2. The Principal Investigator and the Primary Contact will receive an email that contains a link to the study workspace.
3. Log in using your KUMC Online ID and password.
4. You will see the following changes to the workspace:
    a. The study status has changed to **Modifications Required**.
    b. A proviso letter (**Correspondence**) is posted in the upper right corner under the study title.
    c. The **Edit Study** button is now available in the left column.

Provisos that Require Study Documents to be Added or Revised

1. Choose the **Edit Study** function on the left column
2. Use the "**Jump To**" option at the top of the screen to navigate to the tab that has the document(s) to be revised.
3. Choose the **Add** feature to add new documents that were not previously submitted. For example:
    a. On the Consent/ Recruitment tab, choose **Add** to submit a Tracked Changes version of the consent form.
    b. On the Supporting Documents tab, choose **Add** to submit a survey instrument or an approval letter from an ancillary review such as Radiation Safety Committee.
4. Choose the **Update** button to submit revised versions of your documents. For example, on the Consent/Recruitment tab, choose **Update** to attach a Clean Copy of a revised consent form. The original version will be replaced by the document you upload..

Provisos that Require a Narrative Answer

1. For brief responses: After you have made any changes to study documents (see above), type the response into the Notes Box that appears when you select **Submit Changes**.
2. For longer narrative: Create a response letter in a Word document and save it to your desktop or study folder. After you have made any changes to study documents, there will be an option to upload the letter when **Submit Changes** is selected.

Submitting

1. Select **Submit Changes,** attaching a response letter if desired. You will see the status change to "Post Review."
2. After the study is approved, it will appear in your "**Active**" tab of the IRB module. Your approved documents will appear as Finalized documents in the Documents section of the study workspace. Approved consent forms will be stamped with a footer that shows the approval and expiration dates.

Please feel free to call the Research Compliance Office with questions: (316)293-2610