Updating a Study Relying on an External IRB

For studies under an external IRB, the external IRB is responsible for review of all protocol modifications, consent changes, recruitment materials and other study documents. In addition to working with the external IRB, study teams must inform the KUMC IRB if the following changes occur during the study:

- New KUMC principal investigator
- Changes to financial relationships that could create a conflict of interest for the study
- Contractual changes related to payment for study-related injury
- Changes impacting HIPAA privacy or data security
- Changes impacting costs
- New payments to participants if payments were not included in the original submission
- Internal serious adverse events
- Potentially serious issues of non-compliance
- Continuing Review Approval by the External IRB

1. Choose the “Update Study Details” button

2. Describe the update in the dialog box. (If it is a personnel change, please list the full names of who is being added or removed from the study team here.)
3. To update **External IRB Approval.**
   a. In the “Study Update Information” section please indicate that the study approval period is being updated.
   b. Then in the “External IRB” Section, please upload the current Approval Letter from the External IRB in question #3.

4. **For other Modifications, navigate to the Study-Related Documents if there are new/revised documents to submit.**
   a. Choose “Update” if you are replacing the document with a new version
   b. Choose “Add” if you have a new document to add to the study

5. **Navigate forward to finish the submission.** The status on Upper Left will say “Updating Study”

6. In the History Tab, add a Comment requesting the IRB’s review of the changes. In item #3 choose to send an email notification to the IRB Coordinator, as shown below:
7. After IRB has accepts the change, you will get an email notification through the eCompliance system. The system does not allow a new letter to be sent, but acknowledgement will be shown in a public comment.