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

1. **Choose the Update Study Details button**

2. **Describe the update in the dialog box.**

   **Study Update Information**

   1. **Summarize the updates:**

   The sponsor has decided to offer payment for participation.
3. **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

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

   **DO NOT** choose “Finalize Updates” because then the IRB won’t be able to provide a review.

5. 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. After IRB has reviewed and accepted the change, you will get an email notification through the eCompliance system.

6. 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.