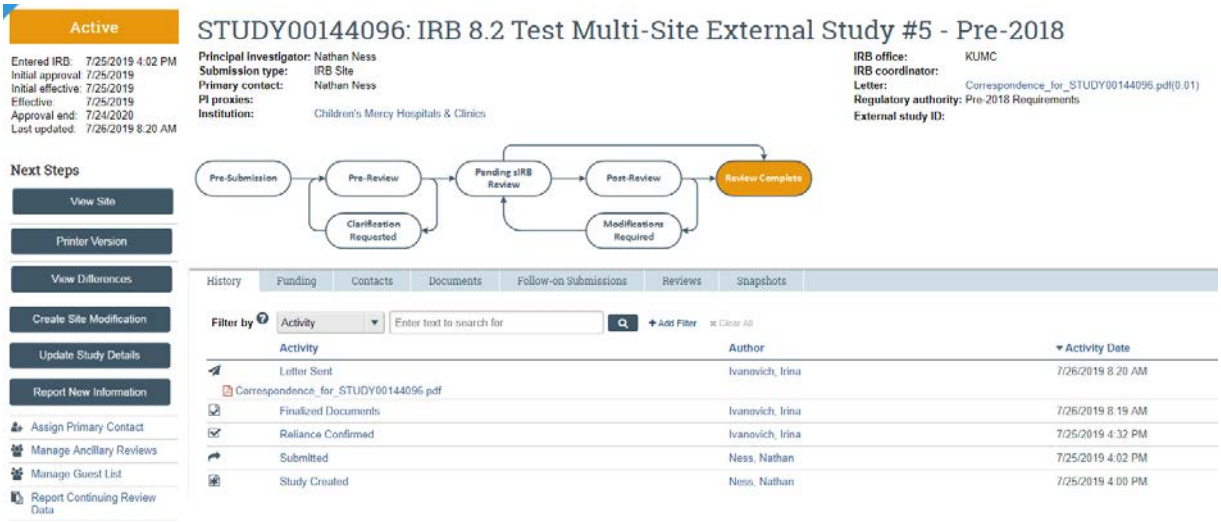
Updating a Study Relying on an External IRB

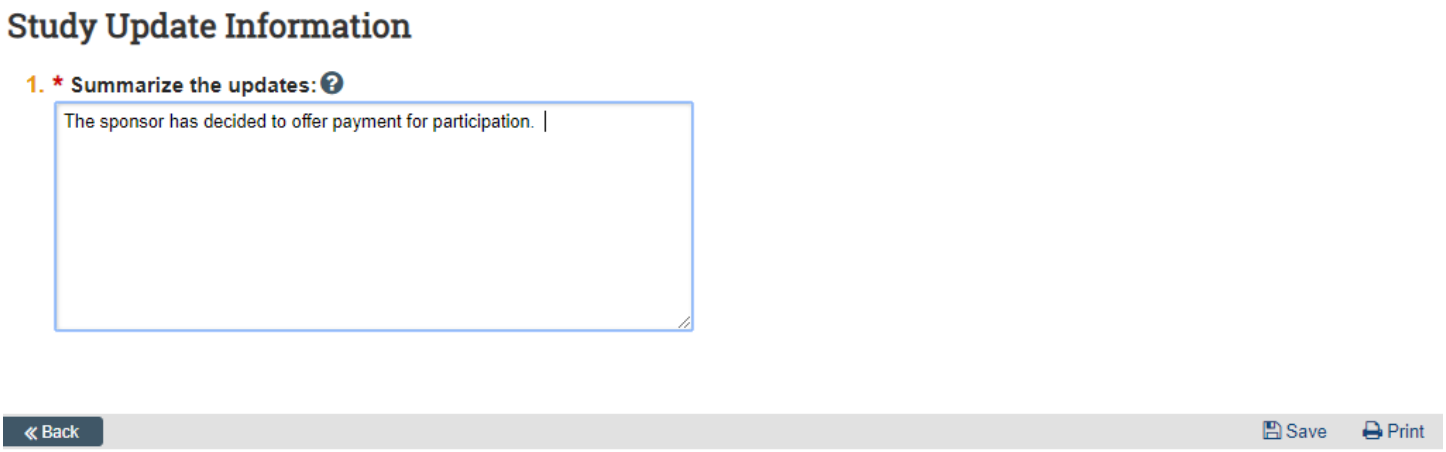
For studies under an external IRB, the external IRB is responsible for review of all protocol modifications, consent changes, recruitment materials and other study documents. In addition to working with the external IRB, study teams must inform the KUMC IRB if the following local changes occur during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

- Changes to the principal investigator or other study personnel
- Additional sites under the KUMC principal investigator
- Updates on conflict of interest disclosures
- Changes that impact any of the KUMC ancillary reviews (such as changes to the amount of radiation used in the study)
- Contractual changes related to payment for study-related injury
- Changes impacting HIPAA privacy or data security
- Changes impacting costs to participants
- Addition of 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 or Study Closure by the External IRB

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

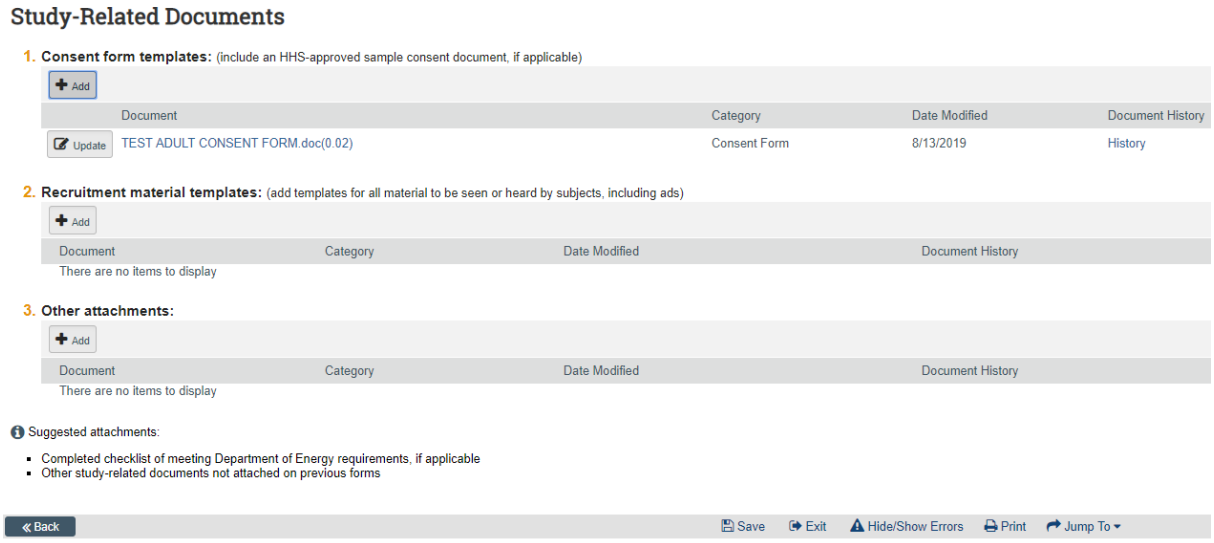


2. **Describe the update in the dialog box.** (PLEASE NOTE: For a personnel change, please list the full names of who is being added or removed from the study team here.)



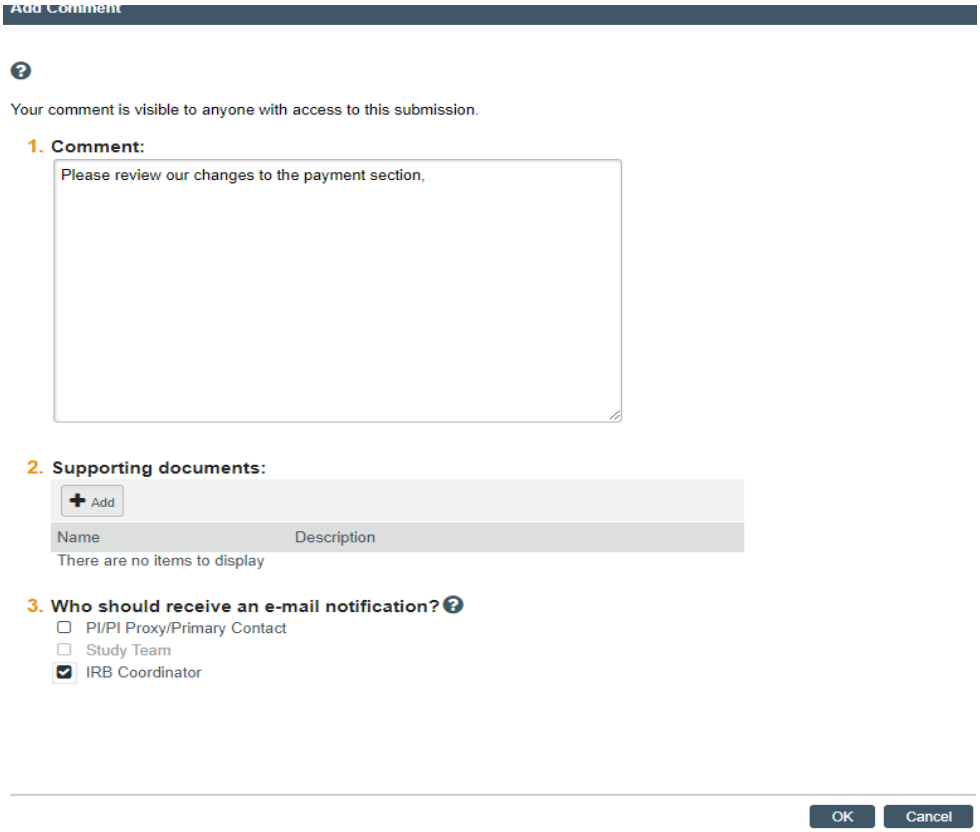
3. To update **External IRB Approval.**
    a. In the "Study Update Information" section please indicate that the study approval period is being updated.
    b. Then in the "External IRB" Section, please upload the current Approval Letter from the External IRB in question #3.

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 a document with a new version
    b. Choose "Add" if you have a new document to add to the study (PLEASE NOTE: When the update is a change in the Principal Investigator please upload communication from the new PI [and if possible the current PI] regarding acceptance of this change.)



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.