

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 any local changes, or revisions to the site-specific boilerplate consent language, occur during the study. These changes should be submitted locally **before** submitting to the external IRB. **Only** reporting study continuation or closure require external IRB review and approval before submitting to the KUMC IRB.

The following changes throughout a study are the most common:

- Changes to the principal investigator or other study personnel
- Updates to conflict-of-interest disclosures (a signed Management plan and tracked consent are required)
- 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
- Continuing Review Approval or Study Closure by the External IRB (the external IRB approval letter is required)
- **Addition** of payments to participants **if payments were not included in the original submission**, or the **removal** of payments to participants **if payments were included in the original submission but will no longer be issued**. (A local submission is not required if there is only a change in a payment amount previously listed within the initial submission of the study.)
- A consent being **newly added** to a study (that was **not** previously reviewed within the initial submission).
- Any KUMC specific recruitment materials. (Approved study wide recruitment documents that will only add local site contact information do not require a local submission.)

Please Note: Internal serious adverse events and potentially serious issues of non-compliance should also be reported, but please report these as **reportable new information (RNI)** and not as an external update to the study.

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

PLEASE NOTE: External Updates should only be entered into the myIRB system when they are ready to be processed by the HRPP team because they are automatically submitted when created. There is no “submit” button.

2. Describe (summarize) the update in #1 under the **“Study Update Information”** heading.

- The summary must explain all changes being made in detail in order for the submission to be processed correctly.
- Some reminders:
 - For a personnel change, please list the full names of who is being added to or removed from the study team. The actions completed on the study team list within the system must match what is listed in the summary.
 - For study continuation or closure please indicate that the study approval period is being updated or the study is being closed.

3. Navigate to **“Local Site Documents”** if there are new/revised documents to include in the submission.

- Choose **“Add”** to add a new document to the study. Do not remove/replace any previous documents. They must all remain part of the study documentation.
- Some reminders:
 - When the update is a change in the Principal Investigator, please upload communication from the new PI regarding acceptance of this change.

- The External IRB Approval of Study Continuation or Study Closure Letter is required to be uploaded as a new document. Sponsor letters cannot be accepted as confirmation of continuation or closure of a study.
4. Navigate forward to finish the submission. The status in the upper left gold box will show ***“Updating Study”***. It has been automatically submitted.
 5. In the ***“History Tab”***, you may add a Comment to provide additional information about the update if necessary. This is also where all communication occurs regarding the submission until it is finalized by the HRPP staff.
 - Add comments in box #1 and in #3 choose to send an email notification to the IRB Coordinator.
 6. The HRPP staff will review the submission. A comment will be added to notify your team if clarifications needed.
 - Clarification will be requested if the submission requires changes before it can be finalized. Reminders are not automatically generated by the system, so if comments regarding changes are left unanswered, then the flow chart bubble will remain ***“Updating Study”***, and the submission not finalized. Therefore, please review all comments sent for external updates to make sure they are fully addressed, and the submission is not left outstanding in the system.
 7. Once the submission has been fully processed and finalized, the orange flow chart bubble will move from ***“Updating Study”*** to ***“Updates Complete”***.

Additional guidance regarding studies under the oversight of an external IRB is also available on the IRB website ***“Reliance Forms and Templates”*** page. The ***“Quick Tips for External Updates”*** is a helpful reference document when deciding if something should be submitted locally for studies relying on an external IRB.