

QUICK TIPS FOR EXTERNAL UPDATES

“Update Study Details”

Once a study has been released to external IRB oversight, updates should be limited to changes to **local context information** only. It is not necessary to submit study-wide changes because these are reviewed and approved by the external IRB on which the study is relying on. Please submit local changes to the KUMC IRB for review prior to seeking approval from the external IRB. When submitting an External Update, it is important for the Summary to list details of all changes being made to the submission because the myIRB system does not show these changes otherwise. **Please do not replace any documents that are in the submission. All new documentation should be uploaded within the Local Site Documents Section by choosing “Add” rather than “Update”. Previous documentation must remain part of the study file throughout the study.**

1. Personnel updates:

- The summary in the myIRB system should list full names (first and last) of people being added to or removed from the study.
- Please make sure to revise the study team list in the myIRB system with the changes listed in the summary. The actions made to the study team list must match what is listed in the summary.
- Before adding anyone to the study team please check that each person is current with CITI Human Subjects training and COI.

2. Change in the Principal Investigator:

- The summary in the myIRB system should include the full names of both PIs.
- Within the myIRB system please revise the Basic Study Information questions to list the name of the new PI and to list “yes” or “no” to any financial interest related to the research.
- If the new PI had been a co-investigator on the study, please remove them from the study team list as a co-investigator. They should only be listed as the PI in the Basic Study Information section in the system.
- The new PI must be current with CITI training and COI.
- Upload correspondence (letter or e-mail) from the new PI regarding acceptance of this PI change.
- Remember to notify the Sponsor and external IRB about this change of PI and obtain their approval.

3. Study continuation or closure:

- The summary in the myIRB system should state if this is a study continuation or closure.
- Upload only the external IRB approval letter for study continuation or closure. No other documentation is required. Upload this by choosing “Add” and not “Update” because previous approval letters must remain part of the study file.

4. Updates on Conflict-of-Interest Disclosures

- The summary in the myIRB system should list the person who has a conflict.
- Please change the response in the myIRB system Basic Study Information to be “yes” for financial interest for the PI (if the PI has the conflict).
- Please change the columns of the study team list in the myIRB system to indicate “yes” for “financial interest” and “no” for “involved in consent” for all who have a financial conflict.
- Please upload the signed Management Plan and revised consent form (that adds the required COI information) into the myIRB system.

For all other local changes including examples specified in #s 5-9 below:

- The summary in the myIRB system should list details of the local change.
- Upload the revised Informed Consent and any other documentation that supports the local change as a new document by choosing “Add” and not “Update”.

5. Changes that impact any of the KUMC ancillary reviews (such as changes to the amount of radiation used in the study)

6. Contractual changes related to payment for study-related injury

7. Changes impacting HIPAA privacy or data security

8. Changes impacting costs to participants

9. 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.

PLEASE NOTE: External Updates should only be entered into the myIRB system when they are complete and ready to be processed by HRPP because they are automatically submitted when created. A comment will be sent within the submission from the HRPP staff to notify your team that the update is finalized or to request clarification if the submission requires changes. Reminders are not automatically generated by the system regarding external updates that require revisions, so if comments regarding changes are left unanswered, then these submissions remain outstanding in the system and not finalized. Please review all comments sent for external updates to make sure they were fully processed. Thank you.

Please don't hesitate to contact the KUMC IRB Reliance Team with any questions: IRBreliance@kumc.edu