

QUICK TIPS FOR EXTERNAL UPDATES

Once a study has been released to external IRB oversight, updates should be limited to those items specified in Step 8 on our webpage under “**Relying on an External IRB**”. A guidance document for submission of local changes to the study “**Updating a Study Relying on an External IRB**” is also provided on the webpage. Please do not submit every study-wide update to KUMC because we are not the IRB of oversight for reliance studies and these updates have already been approved by the External IRB. Only submit **local changes** please. For External Updates, the eIRB system does not show the changes that are being made so all changes need to be listed in the summary please.

1. Personnel updates:

- The summary in the eIRB system should list full names of people being added to or removed from the study.
- Please make sure to revise the study team list in the eIRB system with the changes and not just list them 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 eIRB system should include the full names of both PIs.
- Within the eIRB 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 eIRB system should state if this is a study continuation or closure.
- Upload only the external IRB approval letter for study continuation or closure.

4. Updates on Conflict of Interest Disclosures

- The summary in the eIRB system should list the person who has a conflict.
- Please change the response in the eIRB 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 eIRB 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 eIRB system.

For other **local changes 5-9**:

- The summary in the eIRB system should list details of the local change.
- Upload the revised Informed Consent and any other documentation that supports the local change.

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

Please note that External Update submissions should only be submitted when they are complete and ready to be processed by HRPP. If they are not complete, then a comment is sent from HRPP staff, but if the comment is left unanswered, then these submissions remain outstanding in the system as not finalized. Reminders are not automatically sent by the system regarding external updates, so comments sent need to be read and any outstanding issues addressed please. A comment will be sent once the submission has been finalized.

We welcome your feedback about external IRB updates. Please don't hesitate to contact the KUMC IRB Reliance Team with any questions: IRBreliance@kumc.edu