

# 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 occur during the study. The following changes are the most common:

- Changes to the principal investigator or other study personnel
- Updates to 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
- Continuing Review Approval or Study Closure by the External IRB
- 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.
- Any KUMC specific recruitment materials

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 complete and ready to be processed by HRPP because they are automatically submitted when created.

**Active** STUDY00144096: IRB 8.2 Test Multi-Site External Study #5 - Pre-2018

Entered IRB: 7/25/2019 4:02 PM  
Initial approval: 7/25/2019  
Initial effective: 7/25/2019  
Effective: 7/25/2019  
Approval end: 7/24/2020  
Last updated: 7/26/2019 8:20 AM

Principal investigator: Nathan Ness  
Submission type: IRB Site  
Primary contact: Nathan Ness  
PI proxies:  
Institution: Children's Mercy Hospitals & Clinics

IRB office: KUMC  
IRB coordinator:  
Letter: Correspondence\_for\_STUDY00144096.pdf(0.01)  
Regulatory authority: Pre-2018 Requirements  
External study ID:

**Next Steps**

- View Site
- Printer Version
- View Differences
- Create Site Modification
- Update Study Details
- Report New Information
- Assign Primary Contact
- Manage Ancillary Reviews
- Manage Guest List
- Report Continuing Review Data

Workflow: Pre-Submission → Pre-Review → Pending sIRB Review → Post-Review → Review Complete. Transitions include Clarification Requested and Modifications Required.

Activity	Author	Activity Date
Letter Sent	Ivanovich, Irina	7/26/2019 8:20 AM
Correspondence_for_STUDY00144096.pdf		
Finalized Documents	Ivanovich, Irina	7/26/2019 8:19 AM
Reliance Confirmed	Ivanovich, Irina	7/25/2019 4:32 PM
Submitted	Ness, Nathan	7/25/2019 4:02 PM
Study Created	Ness, Nathan	7/25/2019 4:00 PM

## 2. Describe the update in the dialog box “Study Update Information”.

Number one asks for a summary of the updates. The summary must explain all changes being made in detail in order for the submission to be processed correctly.

- 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.

# Study Update Information

## 1. \* Summarize the updates:

Updating the study approval period|

## 3. Navigate to Local Site Documents if there are new/revised documents to include in the submission:








- Choose “Add” to add this new document to the study

### 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. Do not replace previous versions of the approval letters. (Sponsor letters cannot be accepted as confirmation of continuation or closure of a study.)
- Do not remove any previous documents. They must all remain part of the study documentation.

## Local Site Documents














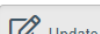


### 1. Consent forms: (include an HHS-approved sample consent document, if applicable)

 Add					
	Document	Category	Date Modified	Document History	
	 TEST ADULT CONSENT FORM_Sponsor Template.doc(0.01)	Consent Form	10/25/2021	History	
	 TEST ADULT CONSENT FORM_tracked.doc(0.01)	Consent Form	10/25/2021	History	

### 2. Recruitment materials: (add all material to be seen or heard by subjects, including ads)

 Add					
	Document	Category	Date Modified	Document History	
	 TEST KUMC SPECIFIC ADVERTISEMENT.doc(0.01)	Recruitment Materials	10/25/2021	History	

### 3. Other attachments:

 Add					
	Document	Category	Date Modified	Document History	
	 TEST KUMC EXT IRB CONT RVW APPROVAL LTR.docx(0.01)	Letters of Support	10/25/2021	History	
	 External IRB Study-Wide Approval Letter(0.01)	Letters of Support	10/25/2021	History	
	 Radiation Safety Committee Approval letter(0.01)	Ancillary Approval Letter	10/25/2021	History	
	 TEST SPONSOR EMAIL.docx(0.01)	Sponsor Correspondence	10/25/2021	History	
	 TEST REQUEST TO RELY.docx(0.01)	Supplemental Application Form	10/25/2021	History	

- 4. Navigate forward to finish the submission.** The status in the upper left gold box will show *“Updating Study”*. There is no choice given to *“submit”*. The update is 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 the box for #1 and in item #3 choose to send an email notification to the IRB Coordinator, as shown below:



Your comment is visible to anyone with access to this submission.

**1. Comment:**

Please review our changes to the payment section.

**2. Supporting documents:**

+ Add

Name	Description
There are no items to display	

**3. Who should receive an e-mail notification? ?**

- PI/PI Proxy/Primary Contact
- Study Team
- IRB Coordinator

OK

Cancel

6. After the HRPP staff has reviewed the change, you will get an email notification through the eCompliance system. 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 before it can be finalized. Reminders are not automatically generated by the system regarding external updates that require revisions, so if comments regarding changes are left unanswered, then the flow chart bubble remains as *“Updating Study”*, and the submission is not finalized. Therefore, please review all comments sent for external updates to make sure they were fully processed and not left outstanding in the system. When the submission is fully processed/finalized the orange flow chart bubble will move from *“Updating Study”* to *“Updates Complete”*. A comment will be added by the HRPP staff to confirm that the update is acknowledged.

**Extra guidance regarding studies under the oversight of an external IRB is also provided on the IRB website *Reliance Forms and Templates* page. This document is called *“Quick Tips for External Updates”*.**