

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

Active

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

History

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. (PLEASE NOTE: For a personnel change, please list the full names of who is being added or removed from the study team here.)

Study Update Information

1. * Summarize the updates: ?

The sponsor has decided to offer payment for participation. |

« Back Save Print

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.)

Study-Related Documents

1. **Consent form templates:** (include an HHS-approved sample consent document, if applicable)

Document	Category	Date Modified	Document History
<input type="checkbox"/> Update TEST ADULT CONSENT FORM.doc(0.02)	Consent Form	8/13/2019	History

2. **Recruitment material templates:** (add templates for all material to be seen or heard by subjects, including ads)

Document	Category	Date Modified	Document History
There are no items to display			

3. **Other attachments:**

Document	Category	Date Modified	Document History
There are no items to display			

Suggested attachments:

- Completed checklist of meeting Department of Energy requirements, if applicable
- Other study-related documents not attached on previous forms

« Back Save Exit Hide/Show Errors Print Jump To

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:



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

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.