IRBManager Quick Start Guide

AMENDMENTS – OTHER CHANGES

GENERAL INFORMATION

Proposed modifications that are not limited to changes in Principal Investigator or other study personnel fall into the “Other Changes” category. Examples of such changes include, but are not limited to, updates to the following areas:

- Study protocol
- Recruitment strategies
- Research study design
- Subject compensation
- Study survey(s) or other instruments;
- Subject identifiers collected for the study, which would potentially impact subject privacy and confidentiality protections;
- Study sites
- Subject population.

STEP BY STEP INSTRUCTIONS

**Step 1:** Please consult the Amendment Submission – Overview & Attachments Quick Start Guide on how to initiate an amendment application.

**Step 2:** Select “Other Changes” when asked to identify the type of amendment application.

**Note:** Multiple categories, including Change in Personnel and Change in PI, may be selected at this stage. This Quick Start Guide is focused on “Other Changes” only.

![Select all changes applicable to the amendment application.](Required)

- [ ] Change in Personnel (Other than PI)
- [ ] Change in Principal Investigator
- [x] Other Changes

**Step 3:** Click “Next”. New form elements will appear similar to that shown on the next page.
Step 4: Provide a brief description of the proposed changes.
You have the option of adding notes to clarify your responses. Do not provide your response to the question in the form of a note.

Step 5: Provide the rationale for the proposed changes.
New form elements will appear similar to that shown below.

Step 6: Answer all applicable questions.
If you select “Yes” to certain questions, you will be asked to provide additional information and will be required to provide respective documents associated with your response on the attachments page, as applicable. See example on the next page.
**Step 7:** Indicate if the proposed changes will affect the IBC requirements of this study. If you respond “Yes”, or are unsure, contact the IBC.

**Step 8:** Indicate if currently approved study documents (informed consent form(s), HIPAA, Protocol, etc.) will require modifications or if there are new study documents associated with this amendment.

**Step 9:** Press “Next”. If you selected “Yes” at **Step 8**, you will be directed to an Attachments Table (similar to the one shown on the next page) to submit the new and/or revised document(s).
Step 10: Select the type of document being attached.

Step 11: Press the “Add Attachment” button and upload the appropriate document. **Name the document as “Clean” or “Track-changes” with the appropriate descriptive title.**

Step 12: Click “Save”.

Repeat Steps 10-12 for as many attachments as needed.

Submitting the Application

Step 13: Press “Next” when you are finished adding attachments and are ready to submit the application. New form elements will appear.

Step 14: Press “Submit”.

If you are the PI who is completing the form, you will be prompted to provide an electronically signature before clicking “Submit.” If anybody other than the PI is completing the form, once the “Submit” button is clicked, an e-mail message will be sent to the PI instructing him/her to open the application, provide an electronic signature and complete the final submission.
After final submission, the applicant will receive the message shown below and the application will be routed to the IRB Office for review.

**SPECIAL NOTE:** If revisions to the application are required, the IRB Office or reviewer will return the application to the study team with instructional notes as shown in the example below. **Please submit your revisions in the actual form (i.e., in the text box) NOT by simply adding a note to the application.** The “Add Note” option is there for providing clarifications or asking questions. If you try to only add a note when a revision to a question is required, you will get an error message and not be able to move forward with resubmitting the amendment.

If you have any questions about IRBManager please contact the LSUHSC-NO Office of Research Services by e-mail:  
IRBOffice@lsuhsc.edu