IRBManager Quick Start Guide

AMENDMENT SUBMISSION - OVERVIEW AND ATTACHMENTS

General Amendment Information:

Amendments are modifications to currently approved studies. Changes include, but are not limited to changes in personnel, change in principal investigator (PI), changes to study protocol, new or revised study documents, updated consent procedure, subject population, addition or removal of study sites.

The IRBManager amendment form should not be used for protocol deviations, reportable events, or study closures. Currently, this information must be provided to the IRB separately on paper forms.

**NOTE:** the IRBManager system is NOT compatible with Internet Explorer (IE) and Microsoft EDGE browsers at this time. You must use Google Chrome or Mozilla Firefox (with Windows and iOS) or Safari (with Apple devices). [Click here](#) for instructions on how to set Chrome as your default browser.

Starting an Amendment Form Procedure:

1. Log into IRB manager: [https://lsuhsc-no.my.irbmanager.com/](https://lsuhsc-no.my.irbmanager.com/)
   - Follow login instructions as listed in the quick start guide found here.

2. Find the study you wish to modify by selecting on **Active** studies to locate it or directly selecting the study under “my studies” column as shown below.

3. Once in the study you wish to modify, click on **Start xForm** on the left side of your screen under "Actions."

↓ Go to next page ↓
Select the Amendment Application xForm by clicking on the form's title.

PLEASE NOTE: To complete the amendment application form, you must be in the specific study for which you want to complete the form.

Once you click on the Amendment Application link, a screen similar to the image below will appear:

Select all changes applicable to the amendment application and press “next”

↓ Go to next page for description of types of changes↓
Description of Type of Changes:

1. Change in Personnel requests are to remove or add study team member(s), other than the PI.
2. Change in Principal Investigator (PI) - processed separately from a change in personnel request. Select this option only if you wish to change the PI.
3. “Other” includes all other modifications, including but not limited changes to:
   - 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.

Once the type of change(s) is selected, click the <Next> button to begin the Amendment Application questions.

Visit our [website](#) for quick guides specific to each amendment type.

Adding Attachments:

Based on your responses to questions throughout the amendment form, you may be prompted to add attachments associated with your amendment. Follow the instructions below to attach associated study documents that require revisions as a result of the amendment:

If new or revised study documents are submitted with the Amendment Application:

**Step 1:** Click “Add Attachment

**Step 2a:** Name the document (include in the title clean or track changes copy)

**Step 2b:** Select the document type **instructions on next page for HIPAA and Informed Consent Forms**

**Step 2c:** Add attachment
Step 3: Click "Attach".

Once you’ve added the attachment, the screen will appear similar to the image below:

If the form was returned to the study team and requires updates to a specific attachment, REPLACE the one requiring revisions with the updated version by clicking the green arrows. (Required)

After listing all attachments, click "Next" to move forward with the amendment application. Ultimately, you will need to click "Submit" for the application to be processed.

Step 4: Repeat this process for as many attachments as you are submitting.

ATTACHING INFORMED CONSENT AND HIPAA FORMS

If your submission includes Informed Consent (ICF) and/or HIPAA form, follow the specific instructions below for the most recent version of these to be stored within the study in IRBManager as reference documents and for the approved versions to be stamped “approved.”

Step 2b: Select the document type - Informed Consent Forms Track Changes

Select “Track Changes Informed Consent Form - All Types” for all track changes versions of informed consent forms regardless of its function (assent, main, pregnant partner etc.) as shown in pictures on the next page.
Once selected and attached, it will look similar to the screen below, listing the document type you selected on the right side of the screen. **Repeat this process for as many track changes ICFs as needed**, always selecting it as the same document type.

**Step 2b: Select the document type - Informed Consent Forms Clean or New**

Select the Specific Consent Form option with the most accurate description and **continue** to select it as that type in the future (Consent - Main Study; Consent - Optional Biospecimen Collection; Consent - Pregnant Partner of Male Subject etc). If you do not select the same document type for that specific form in future submissions, the reference documents within the study will not be correct:
Once selected and attached, it will look similar to the screen below, listing the document type you selected on the right side of the screen:

Repeat this process for as many clean or new ICFs as needed, selecting unique consent document types for each one.

**Step 2b: Select the document type – HIPAA Form Track Changes**

Select “Track Changes HIPAA Form - All Types” for all track changes versions of HIPAA forms regardless of its function (assent, main, pregnant partner etc.) as shown below:

Once selected and attached, it will look similar to the screen below, listing the document type you selected on the right side of the screen. Repeat this process for as many track changes HIPAA forms as needed, always selecting it as the same document type.

**Step 2b: Select the document type – HIPAA Forms Clean or New**

Select the Specific HIPAA Form option with the most accurate description and continue to select it as that type in the future (HIPAA-Main Study; HIPAA – Pregnant Partner; HIPAA –Optional Biospecimen Collection etc.). If you do not select the same document type for that specific form in future submissions, the reference documents within the study will not be correct (see picture on next page):
Once selected and attached, it will look similar to the screen below, listing the document type you selected on the right side of the screen:

Repeat this process for as many clean or HIPAA Forms as needed, selecting unique HIPAA document types for each one.

If you do not follow the process as listed above for consent/assent forms and/or HIPAA forms or follow it inconsistently (i.e., do not select the same document type for that specific form in future submissions) the reference documents within the study will not be correct.

This reference document section in the study is there to help support you in easily identifying current consent/assent/HIPAA documents but it is ultimately the study team that is responsible for ensuring that currently approved forms are being utilized at all times.

**SPECIAL NOTE**: If the form is sent back to the study team and requires revisions to the attachments submitted with the application, be sure to click the green arrows to replace the obsolete version with the one reflecting the IRB’s requested revisions.

A “Replace Attachment” screen will appear for you (as shown on next page) to replace the prior document with the corrected version.
After all required questions are completed and associated documents attached, click the <Next> button.

PI Sign-Off:

If the submitter is not the PI, he/she will be brought to the last screen. Click <Submit> for the form to be sent to the PI for signature.

The PI will then be sent an email requesting review and signature of the amendment application with a link to the form. The PI will review the application, clicking <Next> at the bottom of each page until he/she reaches a page, prompting him/her to select if the amendment is ready for IRB submission or if it needs to be sent back to the original submitter for revisions prior to IRB submission. If the PI selects “Ready for Submission”, he/she will be brought to the PI Signature page which looks like the one pictured below.

Please click <Sign>, entering the prompted information and then click <Next>. The form will not be submitted unless you click <Next> and then <Submit>
Finally, click **Submit** on the last screen.

Once you submit the form you will get the following message:

If you have any questions about IRBManager please contact the LSUHSC-NO Office of Research Services at:

IRBOffice@lsuhsc.edu