IRBManager Quick Start Guide

AMENDMENT SUBMISSION - CHANGE IN PERSONNEL

NOTE: This Quick Start Guide provides instructions for removing and/or adding personnel, other than the Principal Investigator, to a research study. To change the PI for a study, consult the Quick Start Guide – Change in PI.

NOTE: If the Change in Personnel request is for addition of an individual to the research project, first please confirm that the individual is “engaged” in research activities. Someone is engaged in human subjects research if he/she obtains:

1. Data through intervention or interaction with an individual;
2. Identifiable private information about the study subjects; or
3. Informed consent of human subjects for the research.

If the individual is NOT engaged in research by the above definition, his/her participation in the research does not need to be reviewed by the IRB. If the individual is engaged in research, please move forward with your request as described below.

STEP BY STEP INSTRUCTIONS

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

Step 2a: Select “Change in Personnel (Other than PI)” when asked to identify the type of amendment application.

Step 2b: Click “Next”.

You will be directed to a page that provides general instructions as well as a table listing current members of the study team as shown below.
If the person you are want to “remove” is not listed in this table there is no need to continue (since he/she is not listed as a part of the study team). If the person you wish to “add” is already listed, then the request to add them is not applicable since this has already been approved. **Reference this table before proceeding with your requests.**

**Step 3:** Select “Removal of Personnel”, “Addition of Personnel” or both. For each item selected, additional form elements will appear. Instructions for removal of study team members are provided in Step 4 and addition of new members is provided in Steps 5-7.

**Removal of Study Team Members**

For the removal of study team members, make sure they’re listed in the current study team table, then follow the process as detailed in the pictures below:

**Step 4a:** Indicate whether or not this change will require revisions to study documents.

**Step 4b:** Click the "Add Contact" button. A new form element entitled “Add Contact” will appear.
Step 4a: Enter the email address (can be found in the Current Study Team Table) of the individual (other than the PI) you wish to remove and then press “Add Contact.”

If the email address is entered correctly, it will be recognized by the system, as pictured below.

Step 4d: Continue this process for as many study team members you wish to remove by clicking on “Add Contact”.

Step 4e: After the final contact has been added press “Next” and then, in the subsequent form element, press “Submit” for processing.
Addition of Study Team Members

If at Step 3, you selected “Addition of Personnel,” a new form element will appear asking for the affiliation (either Internal or External) of the person(s) being added.

Step 5: Select “Internal,” “External,” or both. Follow Steps 6a-g for adding Internal personnel and Steps 7a-e for adding External personnel.

Addition of Internal Investigators

Step 6a: Indicate whether or not this change will require revisions to already approved study documents (such as informed consent forms, protocols, etc.).

If “Internal” was selected at Step 5, new form elements will appear as shown on the next page.
Addition of Internal Investigators Only.

List the e-mail address of those you wish to add to the study in the table below, clicking “save” after every entry. Repeat for as many internal people you wish to add.

After saving the name, expiration dates will appear in the table. If no dates appear or if “Missing” is listed in a column, it means that that specific training module is either not required, incomplete, or not in the LSUHSC-NO system. Click here for more information regarding training requirements and expiration abbreviations. Attach any applicable training certificates done through a different institution below as needed.

IRB staff will check all training once the form is submitted and follow-up accordingly.

**Internal Personnel Training Table:**

<table>
<thead>
<tr>
<th>E-mail address of new personnel*</th>
<th>BBP HR*</th>
<th>BBP LR*</th>
<th>HIPAA*</th>
<th>COI Research*</th>
<th>Bio*</th>
<th>SBR*</th>
<th>GCP*</th>
<th>Annual*</th>
<th>Action</th>
</tr>
</thead>
</table>

If you received an error indicating “Contact not found,” click the link below to add the contact to IRBManager System. More instructions can be found here.

Only click here if you received an error when entering an e-mail address.

Attach documentation of any human subjects research (HRS) certifications for the internal investigators listed above if done through a different institution (not LSUHSC-NO).

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**Step 6b:** Enter the e-mail address of the person you wish to add to the study in the Internal Personnel Training Table.

**Step 6c:** Click “Save”.

If you receive the error message “Contact not found” when entering an e-mail address this means that the individual is not a contact in the IRBManager System. A person must be listed as a contact in IRBManager before he/she can be added as research team member for a study. Click the link provided (green arrow in the image above) to add the individual into the System. Also, Click here for more instructions on this process. Once the contact is added to the IRBManager System, you may then re-enter the e-mail address to complete the change in personnel form.

For an individual in the IRBManager system, after entry of the email address, the training and annual COI disclosure expiration dates will automatically populate next to the e-mail address if the person is in the LSUHSC-NO compliance system as shown on the image below.
The column headings in the table are abbreviations for the following training courses:
BBP HR - Bloodborne Pathogen High-Risk, KDS Training
BBP LR - Bloodborne Pathogen Low-Risk, KDS Training
HIPAA - HIPAA in Research, KDS Training
COI Research - Conflict of Interest in Research, KDS Training
Bio - Biomedical Research - Basic/Refresher, CITI
SBR - Social & Behavioral Research - Basic/Refresher, CITI
GCP - Good Clinical Practice, CITI
Annual - Conflict of Interest in Research Disclosure, COI Risk Manager

If “Missing” is listed in a column, that means that the course is not required, not assigned, incomplete, or not done through LSUHSC-NO. Dates that are red, indicate that the training has expired. Click here for internal training requirements.

If comparable training was completed through a different institution (for example: documentation of human subjects research (HSR) CITI training) or if applicable training done through LSUHSC-NO did not populate in the table, please add the training completion certificates by clicking the “Add Attachments” button (orange arrow) directly below the training table.

LSUHSC-NO IRB will review training once the form has been submitted and request additional training/assignments and/or provide instructions as appropriate.

Clicking “Save” at Step 6c creates a new email entry line in the Internal Personnel Training Table. Repeat Steps 6b and 6c for all personnel being added.

**Step 6d:** Once the Internal Personnel Training Table is complete, re-enter the e-mail address of the first person being added to the study into the Internal Personnel Details Table (see image below). Select the individual’s role and duties for the study.

<table>
<thead>
<tr>
<th>E-mail address of new personnel</th>
<th>Study Role</th>
<th>Description of Duties</th>
<th>Other Details</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Required)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Re-enter the same e-mail address(es) you listed above into the Internal Personnel Details Table below and select the role, description of duties (all that apply) and other details (if applicable) for each person you wish to add, clicking “save” after every entry.
**Step 6e:** Click “Save.” The table will look similar to the image below. A new email entry line will appear. Repeat for all email addresses inserted in the Internal Personnel Training Table. **All of the e-mail addresses listed in the first table must be listed in the second table.**

![Internal Personnel Details Table](image)

**Step 6f:** Add any additional information/clarifications regarding the addition of internal people in the text box below the Internal Personnel Details Table (optional).

Add any additional information/clarifications regarding the addition of the internal people in the text box below.

**Step 6g:** Press “Next.” If “External” personnel was checked at **Step 5,** you will be directed to the “External Investigator” form elements (**Step 7**).

**Addition of External Investigators**

**Step 7a:** List the e-mail address of the external investigator (some one who is not a LSUHSC-NO employee, faculty or student) you wish to add to the study.

Unlike internal people, you can only list one external e-mail at a time. If you wish to add more than one external person to the study, you can click the “add another external investigator” button at the bottom of the page (see below).
If you received an error indicating “contact not found” when entering an e-mail address, click the link in the form (green arrow) to add the contact to the IRBManager system. For more details regarding this process, click here.

**Step 7b:** Select the Study Role of the external person.

**Step 7c:** Indicate the person’s duties, selecting all that apply, and listing details in the text box if “Other” is selected.

**Step 7d:** List the external’s person home institution (their affiliation).

**Step 7e:** Indicate if LSUHSC-NO will be the IRB of Record for this investigator.

Based on this response, you will be asked a series of questions, which will determine which training modules and documents are needed for processing this request. For more guidance on required documents and agreements to serve as the IRB of Record, click here.
**LSUHSC IRB is NOT the IRB of Record**

If you respond “No,” you will be prompted to provide the following documents in the attachments section:

1. Documentation of the Human Subjects Research (HSR) training completion (CITI or comparable HSR training report), and
2. IRB approval of the study from the external investigator’s IRB of record (e.g., home institution).

- Click “Add Attachment” to provide the required attachments.
- Then press the “Add Another External Investigator” button to repeat the process if you want to add another person.
- When finished adding external personnel, press “Next” to move forward.

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**LSUHSC IRB is the IRB of Record**

If you respond “Yes,” you be asked a series of questions and the person will be required to meet specific training and documentation requirements depending on your responses.

A. **Gratis Appointment?** - If the external investigator has a gratis appointment with LSUHSC-NO, then no additional agreements will be required. For external investigators that do not have a gratis appointment, an agreement (either an IRB Authorization Agreement or an Individual Investigator Agreement) will need to be in place prior to moving forward with this amendment application (see below).

B. **Conducting Research on LSUHSC-NO Campus?** - If, yes, additional training modules are required (KDS – HIPAA Privacy and KDS- Bloodborne Pathogen or comparable training if done through a different institution).
If you indicate that the agreement is not in place, you can either “save” the application and return to completing this form once agreements are complete or remove this person from the amendment application to move forward and submit the request to add him/her at a later time. Click here to access template IAA and IIA documents and instructions for executing the agreements.

- Enter the training expiration dates for applicable modules, based on external investigator requirements, found here.

- Attach copies of completion reports if done through a different institution (Not LSUHSC-NO KDS or LSUHSC-NO CITI)

LSUHSC-NO IRB will review training once the form has been submitted and request additional training/documentation and provide further instructions as needed.
After providing required attachments, press the “Add Another External Investigator” button if you want to add another person.

When you are done adding external personnel, press “Next” to move forward.

Changes in Currently Approved Study Documents

If you previously indicated that this Change in Personnel request requires that modifications be made to currently approved study documents (at Steps 4a and 6A), you will be directed to an Attachments Table (similar to the one shown below) to submit the revised document(s).

**Step 8a:** Select the type of document being attached.

**Step 8b:** Press the “Add Attachment” button and upload the appropriate document. **Name the document as “Clean” or “Track-changes” with the appropriate descriptive title.**

**Step 8c:** Click “Save”.

Repeat Steps 7a-c for as many attachments as needed.
Submitting the Application

**Step 9a:** Press "Next" when you are finished adding attachments. You will be directed to the final screen as shown below.

![Form Submitted](image)

**Step 9b:** Press "Submit" if the application is ready for submission. Once you submit the form you will receive the following message:

![Form Submitted](image)

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

IRBOffice@lsuhsc.edu