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About this Document

This document provides the instructions for:
  Submitting changes to non-key personnel listed on an IRB protocol.
Before You Begin

KC Protocol > Protocol Tab & Personnel Tab & Notes & Attachments Tab

Before you begin the process of adding Non-Key study personnel in KC IRB you should do the following:

Review the information within 3 tabs (Protocol, Personnel, and Notes & Attachments) for any changes needed.

If the only change noted is the need to add or remove one or more IU affiliates as Non-Key, Interacting or Non-Key, Not Interacting, you may proceed with a Non-Key Personnel update.

a. If you find that other areas of the protocol require changes, please see the instructions for submitting an Amendment to your approved protocol.

Confirm that the individual(s) you want to add meets the definition of Non-Key (See this link)

Determine whether the individual(s) will be interacting with subjects

Confirm the personnel have completed the requirements for participation in the research (see HSO website: Researcher Responsibilities)

Please note that the following changes are NOT allowed to be submitted as Non-Key Personnel updates and require a full amendment submission:

a. Change study personnel from Non-Key (Interacting or Not Interacting) to a role of Key Personnel, Co-PI Student/Fellow/Resident or Principal Investigator(PI)

b. Addition or removal of Key Personnel or Co-PI Student/Fellow/Resident

c. Changing the PI

d. Addition or removal of any personnel who are not affiliated with IU
1. Login to KC IRB
2. Click Researchers tab
3. Select Amend or Renew IRB Protocol
4. The Protocol Lookup screen will appear
5. A list of Protocols which may be amended or renewed will appear below the possible search fields.
6. Locate the Protocol you wish to amend and click on the **perform action** link to the left of the Protocol #
7. The Protocol will open to the Protocol Actions tab and the Request an Action folder will expand
   a. Click show on Create Amendment
      i. In the text box next to Summary, enter ‘Non-Key personnel update’, and indicate the personnel being added and/or removed
      ii. Below the Summary, in the Amend section:
         1. Check the box for Personnel Tab
      iii. Click create
8. The Questionnaire tab will open, and the Amendment Questionnaire will populate on this tab automatically under Submission Questionnaires.
   a. If you are only making changes to non-key personnel, click Yes.
   b. If you are making any other changes, including changing an investigator's status from Key to Non-Key, you must click No and submit a complete amendment instead of a non-key update.

9. Click [update button image] to save changes.
   a. When all required questions have been answered, the Questionnaire folder heading will change from "(Incomplete)" to "(Complete)."

**NOTE:** Multiple Questionnaires are used in KC, but not all are required for each study. Any Questionnaires that don’t apply to your study will appear under Read-Only Questionnaires at the bottom of the page.
Personnel Tab

KC Protocol > Personnel Tab

10. Click on the **Personnel** tab
    a. To add study personnel, click to search for an **IU User ID** (includes IU students, faculty, etc.) or **No IU User ID Search** (an affiliate without an IU account).
       i. If known, enter username (this is the fastest search)
       ii. If unknown, search by another value, such as Last Name, using an * (e.g., Johnson*).
       iii. Click search
       1. If entry is not found for affiliated individual with No IU User ID, see the training guide for The Address Book
       iv. Click return value link
    b. When value is returned, select the appropriate **Protocol Role (Non-Key, Interacting or Non-Key, Not Interacting)** from the drop-down list and click add person.
    c. Click **show** on the person’s folder, then click **show** on **Person Details** subsection.
       i. Please Note: If you need to change the role assigned, you can select a new role under Person Details. Use **update view** to update after a protocol role is changed.
Personnel Tab

KC Protocol > Personnel Tab > Person Details

ii. Select **Affiliation Type** *(Affiliated if from No IU User ID lookup)*

iii. **Viewing Investigator Requirements.** The Personnel tab will be enhanced to allow users to see whether investigators have completed the COI and CITI requirements at one glance. All investigators must complete applicable requirements before this submission can be approved.
   1. Investigators who still need to complete a requirement will be highlighted red with an X.
   2. Investigators who have completed both requirements will be highlighted green with a check mark.
   3. Investigators without an IU username will display in black text.

d. Repeat steps to add Non-Key Personnel until all are listed. **Note that the same person should not be listed twice, with two different personnel roles.**

e. Click **show** on **Contact Information** and review the contact information under each person’s folder. If alternate contact information should be provided that is specific to this protocol, make the changes and **save**.
**Personnel Tab**

**KC Protocol > Personnel Tab > Contact Information**

- **Sullivan, Victor**
  - **Protocol Role:** Principal Investigator
  - **Affiliation Type:** IU
  - **Trained:** No (Missing COI and CITI training)

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**f.** If an error was made and a non-key investigator entry needs to be removed, click within the **checkbox** that appears at the left of the person’s folder label to select the item(s). A check mark appears within the checkbox to indicate the item is selected.
  
  i. Click the **delete selected** button at bottom of page.
  
  ii. Click within the checkbox again to clear the mark if you want to deselect the item.

**g.** Click **show** on **Conflicts of Interest** folder, beneath all the Personnel folders.
  
  i. Review and respond to all questions as they apply to the protocol personnel and this research study.
  
  h. Click the **save** button at the bottom of the page.

**10.** Click on the **Protocol Actions tab**
  
  a. Click **show** on the **Request an Action** folder.
  
  b. Click **show** on **Submit for Review**
  
  c. Select **Submission Type** to **Amendment**.
  
  d. Select **Submission Review Type** of IRB Review Not Required.
Data Validations

KC Protocol > Protocol Actions Tab > Data Validation

e. Click submit

11. KC IRB will validate some of the information entered (e.g. check for empty fields, required responses, investigator training, etc.) and will return an error or warning message at the top of the page, above the folders.
   a. If this happens, the Data Validation folder will expand
   b. The system will return any validation errors, warnings, unit business rules errors, and unit business rules warnings.
   c. To correct any errors or address any warnings, click on the link provided (fix button on the right hand side), which will allow you to navigate to the portion of the document containing the error where you can view messages and make corrections.
   d. Once there are no validation or warning errors present, repeat steps above to submit the Non-Key Personnel update.
Post Submissions Tab

Once a protocol has been submitted, if you need to make changes to or withdraw the submission, please contact the Human Subjects Office at irb@iu.edu, referencing your KC IRB protocol number.