RENEW & AMEND A PROTOCOL
TRAINING GUIDE
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Hyperlinks
The Table of Contents “text” has active hyperlinks. Click to jump to any page in this document.

Return to the Table of Contents button
There is a “return” button at the bottom of every page to help you return to the Table of Contents.
About this Document

This document provides the instructions for:

Creating and submitting a renewal, which in KC IRB will be entered as a renewal with amendment, for continuing IRB approval of a protocol.
1. Login to KC IRB
2. Click **Researcher** tab at the top of the screen.
3. Select **Amend or Renew IRB Protocol**
   a. The Protocol Lookup screen will appear
   b. A list of Protocols which may be renewed will appear below the possible search fields.
   c. Locate the Protocol you wish to renew and click on the **perform action** link to the left of the Protocol #
Before You Begin

KC IRB Protocol

**Before you begin the renewal submission in KC IRB you should do the following:**

Review the information on the Protocol, Personnel, and Notes & Attachments tabs for any changes needed.

a. Review current versions of study documents for changes needed.

b. If applicable, make updates to study documents with 'tracked changes' and have those versions ready for upload into KC IRB.

c. Even if no changes are needed to information within KC IRB or the attachments to the protocol, you will always create a Renewal with Amendment in KC IRB so that stamped approved documents can be uploaded.

Review the status of the protocol (found on the Protocol tab> Status & Dates folder) to determine if the status should be updated. You will be required to indicate the protocol and status of enrollment of subjects while completing the renewal submission in KC IRB.

a. If the protocol status is **Active-Open to Enrollment**, it may remain Active-Open to Enrollment, or it may change to Active-Closed to Enrollment.

b. If the protocol status is **Active-Closed to Enrollment**, it may remain Active-Closed to Enrollment, or it may change to Active-Data Analysis Only under the following conditions:
   i. the study must have been reported to the IRB previously as data analysis only using the Closed to Enrollment renewal form; and
   ii. no IRB submissions (including amendments or changes to study personnel) were submitted since the previous review.

   ○ If the protocol status is **Active-Data Analysis Only**, it may remain Active-Data Analysis Only if no IRB submissions (including amendments or changes to study personnel) were submitted since the previous review.

   ○ The protocol may be re-opened to enrollment by formally submitting an amendment along with the renewal.

   ○ If the protocol status is **Expired**, and you are unsure of the status of your study before it expired, please contact the Human Subjects Office.

See our website for guidance on Renewals (http://researchadmin.iu.edu/HumanSubjects/hs_fullboard.html) or contact the Human Subjects Office for additional assistance.
Personnel Tab

Viewing Investigator Requirements

- Drake Nathan *
- Fisher, Elena
- Sullivan, Victor

Investigators who still need to complete a requirement will be highlighted red with an X.
Investigators who have completed both requirements will be highlighted green with a check mark.
Investigators without an IU username will display in black text.

Viewing investigator requirements

The Personnel tab allows 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.
4. Return to the Protocol Actions tab and click show on the Request an Action folder
   a. Click show on Create Renewal with Amendment
   b. In the Summary text box, enter a brief statement about the renewal, including the reason for the amendment if the renewal includes changes to the protocol information in KC and/or existing study documents
      i. Below the Summary, in the Amend section, check the box(es) next to the area(s) of the KC IRB folders where changes are needed, if any.
         1. Always select the ‘Attachments & Notes’ box.
         2. You will only be able to make changes or additions to the KC IRB folders that are selected in this section.
   c. Click create
5. The Questionnaire Tab will open, and the Questionnaires required for Renewals will populate on this tab automatically under Submission Questionnaires.
   a. Depending on the specific question and your answer, additional questions may appear and other questions that don’t apply may disappear. For example, on the Changes & Amendments folder, checking the box indicating the renewal does include an amendment will open additional questions regarding the proposed changes and whether they impact risk to subjects.

6. Click at the end of the Questionnaire 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.
7. Click on the main **Protocol** tab to make any necessary changes.
   a. Click **show** on the necessary folders within the **Protocol** tab and make the changes to the protocol information requested with the amendment, if applicable.
   b. Click **Save**

8. Click on the **Personnel** tab to make any necessary changes.
   a. To add study personnel:
      i. Search for individuals using IU User ID first, even if you think the individual may not have an IU username. Click **search** to search for an **IU User ID** (includes IU students, faculty, affiliates, etc.).
      1. If known, enter username (this is the fastest search)
      2. If unknown, search by another value, such as Last Name, using an * (e.g., Johnson*).
      3. Click **search**
      4. Click **return value link**
**Personnel Tab**

KC Protocol > Personnel Tab

ii. If you do not find the person via IU User ID, search by clicking next to **No IU User ID Search**.
   1. If known, enter username (this is the fastest search)
   2. If unknown, search by another value, such as Last Name, using an * (e.g., Johnson*).
   3. Click search
   4. Click return value link

iii. If you do not find the person via No IU User ID Search, please refer to the Quick Reference Guide – **Accessing & Creating a New Rolodex Entry**.

iv. When value is returned, select the appropriate **Protocol Role** from the drop-down list and click **add person**.

   NOTE: Co-PI Student/Fellow/Resident role should only be selected for student-directed projects to list the student investigator.

b. Click **show** on the person’s folder, then click **show** on Person Details tab.
   i. Confirm Protocol Role. If an incorrect role was previously selected, choose the appropriate role from the drop-down and click.

ii. Select **Affiliation Type**
   1. If the individual is IU an faculty member, staff, or student, or has an IU username, choose IU.
   2. If the individual is an IU an faculty member, staff, or student and does not have an IU username, but is not an IU faculty member of an institution which utilizes the IU IRBs (e.g. IU Health, Wishard/Eskanazi Health, Regenstrief, Roudebush VAMC), choose Affiliated.
   3. If the individual is not affiliated with IU or an institution which utilizes the IU IRBs (see above), choose Non-Affiliated.

iii. **Lead Unit** should automatically populate under the **Unit Details** section of the **Principal Investigator’s** section.

iv. **Unit Details** will also automatically populate for any Investigator with an IU username.
   a. If it doesn’t or to change it, click **show** on Unit Details subsection and click to search for a different unit.
   b. Click return value link
   c. Investigators may be associated with multiple units, but only one may be selected as **Lead Unit** per protocol.

v. Repeat steps to add study personnel until all are listed. Note that the same person cannot be listed twice, with two different personnel roles.

vi. Click **save**.

   c. To delete study personnel, click within the checkbox that appears to the left of the person’s folder label to select. A check mark appears within the checkbox to indicate the item is selected. Click within the checkbox again to clear the mark if you want to deselect the item.
   i. Click the **delete selected** button at the bottom of the page.
   d. Update the Conflicts of Interest questions folder, if applicable, and click **update**.
Notes and Attachments Tab

KC Protocol > Notes and Attachments Tab > Attached Items

9. Click on the Notes & Attachments tab, and click show on the Protocol Attachments folder to review the Attached Items subsection
   a. Click on the show button of an attachment to: view, replace, or delete.
      i. To view an attachment, click on view, and select Save or Open to view the file.
      ii. To replace an attachment, click on replace.
         1. This removes the attachment, and you can Browse for a new File Name.
         2. Locate the file and click Open to attach.
         3. Update the Description field to indicate the attachment was changed, such as “ICS 7/31/2014 A003”
   iii. To delete an attachment, click on delete.
      1. A question will appear: Are you sure you would like to delete the following attachment: XXXXX?
      2. Click yes or no.

NOTE: Document version dates should only be updated when revisions are made. For example, if the R005 submission isn’t changing the consent, the Description field for that document should not be updated.
b. To add new documents to the protocol (e.g., DSMB report, new consent):
   i. Select the Attachment Type, in the Add Protocol Attachment subsection
   ii. Enter a Description, such as “ICS Spanish 7/31/14 A004
   iii. Click Browse for File Name search
   iv. Locate the file and click Open to attach
   v. Click add when file returns

c. Repeat above steps for any new attachment to be added to the protocol with this amendment, if applicable.

d. Upload Zip documents
   Several attachments can be uploaded with one click. Use the upload zip button to upload all documents from a zip file identified by the user. Once documents are uploaded, users simply need to update the Attachment Type and Description for each document, and then save.

e. The number of Protocol Attachments is indicated on the folder label in parentheses.
10. The Custom Data Tab is for Human Subjects Office staff use only. Investigators cannot enter or change any information here.

11. The Medusa Tab allows cross-reference to other e-docs within KC; no action on this tab is required by investigators for IRB submission.
12. Click on the Protocol Actions tab and click on the Request an Action folder.
   a. Click show on Modify Amendment Sections, if you need to make changes to an area of the protocol not selected initially
   b. Modify the Amendment Summary as needed
   c. Check the boxes for any additional areas to Amend. **WARNING:** If you de-select a box you checked previously, any changes made to that section of the protocol will not be saved once you click the update button.
   d. Click update
   e. Click on the necessary tabs and make any additional changes to the protocol information requested with the amendment.

13. Once all updates being requested with the amendment are complete, return to the Protocol Actions tab
   a. Click show on Request an Action
   b. Click show on Submit for Review
   c. Select Renewal with Amendment
   d. See the chart below in order to determine the correct Submission Review Type, and Checklist items
   e. Click submit

<table>
<thead>
<tr>
<th>If your Protocol Type (see Protocol Tab) is:</th>
<th>Select Submission Review Type of:</th>
<th>Select the following Checklist categories:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Expedited</td>
<td>Expedited</td>
<td>1-7, as they apply to the original or amended research</td>
</tr>
<tr>
<td>Full Board</td>
<td>Expedited</td>
<td>8 or 9, as applicable</td>
</tr>
<tr>
<td>Full Board</td>
<td>Full</td>
<td>N/A</td>
</tr>
</tbody>
</table>
14. 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 renewal with amendment for review.
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.