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 on:
Creating and submitting an amendment to an IRB protocol.
1. Login to KC IRB
2. Click Researcher tab at the top of the screen.
3. Select Amend or Renew IRB Protocol
4. The Protocol Lookup screen will appear
5. A list of Protocols which may be amended 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 #
Before you begin the amendment process in KC IRB you should do the following:

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

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

Make updates to study documents with ‘tracked changes’ and have those versions ready for upload into KC IRB.

**FOR EXEMPT PROTOCOLS ONLY:** No Amendment Questionnaire is Required.
7. The Protocol will open to the Protocol Actions tab, and the Request an Action folder will expand.

8. Click show on Create Amendment.
   a. Enter a Summary of the purpose for the amendment. Be as specific as possible, including any Questionnaires that are being revised, study personnel being added or removed, etc.
   b. 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. You will only be able to make changes to the KC IRB folders that are selected in this section, and you must select at least one area.
   c. Click create.

NOTE: If amending an exempt protocol which was submitted prior to the Questionnaire implementation, you are not required to complete the Questionnaire questions unless desired.

   a. If you do not wish to complete the questionnaire, do NOT check the ‘Questionnaire’ checkbox. Instead, make necessary updates to your existing Exempt Research Checklist and replace the existing form on the Notes & Attachments tab
   b. If you wish to utilize the questionnaire functionality, check the ‘Questionnaire’ checkbox and answer the questionnaire questions


9. The Questionnaire tab will open, and the Amendment Questionnaire 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, clicking “No” for the initial amendment question opens the remainder of the amendment questions.

10. Click **[update]** 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.

12. 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**
13. 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 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/Eskonazi 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.
14. Click on the **Notes & Attachments** tab, and click 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.”

   **NOTE:** Document version dates should only be updated when revisions are made. For example, if the A003 submission isn’t changing the consent, the Description field for that document should not be updated.
Notes & Attachments Tab

KC Protocol > Notes & Attachments Tab

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.

b. To add new documents to the protocol (e.g., 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”. Be sure to add the amendment number so revised documents are easily distinguished on the Protocol Summary Report.
   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.
d. **Upload Zip documents**
   Several attachments can be uploaded with one click. Use the upload zip 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.
Custom Data & Medusa Tabs

KC IRB Protocol > Custom Data & Medusa Tabs

1. The Custom Data Tab is for Human Subjects Office staff use only. Investigators cannot enter or change any information here.

2. The Medusa Tab allows cross-reference to other e-docs within KC; no action on this tab is required by investigators for IRB submission.
13. Click on the Protocol Actions tab
   a. Click show on Request an Action.
   b. If you need to make changes to an area of the protocol not selected initially, click show on Modify Amendment Sections (under Available Actions).
      i. Modify the Amendment Summary as needed
      ii. 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.
      iii. Click update
   c. Click on the necessary tabs and make any additional changes to the protocol information requested with the amendment.
14. 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 Submission Type of Amendment.
   d. Select the Submission Review Type
      i. If you choose Exempt or Expedited, a Checklist will appear.
      ii. The checklist boxes may be pre-checked based on the initial submission and/or previous amendments.
   e. See the chart below in order to determine the correct Submission Review Type, and Checklist items
   f. Click submit

<table>
<thead>
<tr>
<th>Protocol Type (Protocol Tab)</th>
<th>Select Submission Review Type of</th>
<th>Select the following Checklist categories:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exempt</td>
<td>Exempt</td>
<td>1-6, as applicable to the original or amended research</td>
</tr>
<tr>
<td>Expedited</td>
<td>Expedited</td>
<td>1-7, as applicable to the original or amended research</td>
</tr>
<tr>
<td>Full Board or HUD</td>
<td>If the Amendment is considered a Minor Change in Approved Research, choose Expedited.</td>
<td>46.110(B)(2) Minor Changes in previously approved research</td>
</tr>
<tr>
<td></td>
<td>If the Amendment is considered a Major Change in Approved Research, choose Full Board.</td>
<td>N/A</td>
</tr>
</tbody>
</table>

Please visit our website at http://researchadmin.iu.edu/HumanSubjects/hs_fullboard.html, under Amendments, to determine whether your amendment represents a minor or major change.
Data Validation

KC Protocol > Protocol Actions > Data Validation

15. 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 amendment for review.
Post Submission Action

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.