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Hyperlinks
The Table of Contents “text” has active hyperlinks. Click to jump to any page in this document.

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About this Document

This document provides the instructions on:
How to copy a Protocol in KC IRB.
### Copying a protocol in KC-IRB

If an investigator routinely works with the same study team members or at the same study sites, using the “copy” function will save time when creating new protocols to submit for IRB review. This allows investigators to use an existing study as a template for a new study, maintaining information that will stay the same and revising elsewhere as needed. Study teams should note that not all information from an existing protocol will copy to the new protocol. A summary table of what is and isn’t copied is below.

<table>
<thead>
<tr>
<th>Copied</th>
<th>Not Copied</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Header</strong></td>
<td>Status, Protocol Number, Document ID</td>
</tr>
<tr>
<td><strong>Protocol tab</strong></td>
<td></td>
</tr>
<tr>
<td>Protocol Type, PI and Lead Unit, Title, Additional Information,</td>
<td>Status and Dates</td>
</tr>
<tr>
<td>Organizations, Funding Sources, Participant Types</td>
<td></td>
</tr>
<tr>
<td><strong>Personnel tab</strong></td>
<td></td>
</tr>
<tr>
<td>Principal Investigator, Co-PI/Student/Fellow/Resident, Key Personnel,</td>
<td>Completed Conflict of Interest questionnaire</td>
</tr>
<tr>
<td>Non-Key Personnel</td>
<td></td>
</tr>
<tr>
<td><strong>Permissions tab</strong></td>
<td></td>
</tr>
<tr>
<td>Study Managers / Correspondents</td>
<td>Aggregators</td>
</tr>
<tr>
<td><strong>Questionnaire tab</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Completed questionnaires</td>
</tr>
<tr>
<td><strong>Notes &amp; Attachments tab</strong></td>
<td>Protocol Attachments, Notes</td>
</tr>
<tr>
<td><strong>Protocol Actions tab</strong></td>
<td>All fields</td>
</tr>
<tr>
<td><strong>Custom Data</strong></td>
<td>All fields</td>
</tr>
<tr>
<td><strong>Medusa tab</strong></td>
<td>All fields</td>
</tr>
</tbody>
</table>
To copy the properties of an existing protocol:

1. Find the study whose information you want to start with.
   a. Go to the main KC-IRB page and search by protocol number or PI name.
2. From the list of studies returned on the Protocol Lookup page, click the “edit” or “view” option for the study you want to use.
3. Click on the Protocol Actions tab.
4. A “Copy to New Document” folder will appear; click “show,” then click the “copy protocol” button.
5. A new protocol will be created with a new Protocol number and the protocol details from the previous study. Changes should be made as needed for the new study, specifically:
   a. Protocol tab
      i. Confirm/revise Protocol Type
      ii. Revise the study title
iii. Confirm/revise the Additional Information folder
   1. Click “show” to open the tab.
   2. Add/remove IND or IDE number(s).
   3. Add/remove the Sponsor’s protocol number in the “Reference ID2” field.

iv. Confirm/revise the Organizations folder
   1. Click “show” to open the tab and review the selected performing organization(s) and performance site(s).
      a. To remove a listed site, click “delete organization” for that item.
      b. To add new organizations/sites, click the search button on the Add line.
         i. On the Organization Lookup page, enter the site name in the Organization Name field (e.g., “Riley”), and click the “search” button.
         ii. Select the appropriate site from the list of returned results, and click “return value.”
         iii. Select the Organization Type from the drop-down menu.
         iv. Click “add.”
Protocol Tab

KC Protocol > Protocol Tab > Funding Sources & Protocol Types

**v. Confirm/revise Funding Sources folder**
1. Click “show” to open the tab and review the selected information.
2. To remove a listed source, click “delete” for that item.
3. To add a source, select Funding Type from the drop-down menu.
   a. Click the search button under Funding Number.
   b. On the Sponsor Lookup page, use the Sponsor Name field (e.g., *National*) or the Acronym field (NIDDK), and click the “search” button.
   c. Select the appropriate entity from the list of returned results, and click “return value.”
   d. Click “add.”

**vi. Confirm/revise Participant Types folder**
1. Click “show” to open the tab.
2. To remove a subject type, click “delete” for that item.
3. To add a subject type, select Type from the drop-down menu, enter the Count (if applicable), and click “add.”
4. Confirm/revise the Total Count.
b. Personnel tab
   i. Ensure Principal Investigator is correct.
      1. To remove the previous study PI completely, click the checkbox to the left of his/her name. Click the “delete selected” button.
      2. To retain the previous study PI in a different role, click “show” to the right of their name.
         a. Click “show” next to Person Details.
         b. Select the new Protocol Role from the drop-down menu.
         c. Click “update view.”
      3. To add a new person to the Personnel tab to serve as PI, click the User ID Search button.
         a. Enter name (Smith*) or user name (smithabc) in the appropriate field and click “search.”
         b. From the list of results returned, click “return value” for the appropriate person.
         c. Select “Principal Investigator” from the Protocol Role drop-down menu, and click “add person.”
ii. Ensure other study personnel are correct
   1. To remove from the Personnel list completely, click the box next to his/her name for all affected investigators.
      Click the “delete selected” button.
   2. To retain in a different role, click “show” to the right of the name.
      a. Click “show” next to Person Details.
      b. Select the new Protocol Role from the drop-down menu.
      c. Click “update view.”
   3. To add a new person(s) to the Personnel tab, click the User ID Search button.
      a. On the KcPerson Lookup page, enter name (Smith*) or user name (smithabc) in the appropriate field
         and click “search.”
      b. From the list of results returned, click “return value” for the appropriate person.
      c. Select the appropriate option from the Protocol Role drop-down menu, and click “add person.”
      d. Repeat until all Personnel are listed.

iii. For the “Conflicts of Interest (Incomplete)” line item, click the “show” button and complete the questions.
c. Permissions tab
   i. Review the persons listed to receive study communications.
      1. To remove a listed person, click “delete” next to that name.
      2. To add a new person, click the search button under User Name.
         a. On the KcPerson Lookup page, enter name (Smith*) or user name (smithabc) in the appropriate field
            and click “search.”
         b. From the list of results returned, click “return value” for the appropriate person.
         c. Select the appropriate option from the Role drop-down menu, and click “add.”
      3. Repeat until all appropriate persons are listed.
Notes and Attachments Tab

KC Protocol > Notes and Attachments Tab

d. Notes & Attachments tab
   i. Upload all study documents, as usual. No previous documents will copy to the new study.
e. When the new protocol submission is accurate and complete, go to the Protocol Actions tab to submit for review, as usual.
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.
Additional Information about KC IRB

http://researchcompliance.iu.edu/hso

KC IRB Training Guides and Training Videos.
Additional Training Guides and Training Videos can be found at the Indiana University Office of Research Administration website.

http://researchcompliance.iu.edu/hso