NEW PROTOCOL - NON-HUMAN SUBJECTS RESEARCH 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:
Instructions for creating and submitting an application for non-human subjects research.
1. **Required Fields for Saving Document** folder. Enter:

   a. **Protocol Type** = Not Human Subject Research
   b. **Title**
   c. **Principal Investigator**
      i. Click for **IU User ID Search** and search for PI
         1. If known, enter username (this is the fastest search)
            a. If unknown, search by another value using an "*" to
            2. Click search
               3. Click return value link
      ii. If the PI does not have an IU User ID, he/she must obtain one before the study can be submitted. Please review the Quick Reference Guide - Accessing KC IRB for instructions on requesting an IU computing account.
   d. The PI’s **Lead Unit** should automatically populate.
      i. If it doesn’t or to change it to the unit associated with this research, click to search for a different unit or type the Unit directly in the field.
**Protocol Tab**

KC IRB Protocol > Protocol Tab > Status & Dates

- **Participant Types**
  - **Status & Dates**
  - **Protocol #**: 1403155660
  - **Protocol Status**: Pending / In Progress
  - **Approval Date**: Generated on Approval
  - **Last Approval Date**: Generated on Renewal Approval
  - **Initial Submission Date**: Generated on Initial Submission

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- e. Click the **save** button at the bottom of the page under the list of folders. You may wish to make note of the Protocol #, located at the top of the page in the document header area, or in the Status & Dates folder.
  - i. If you want to return to the protocol for future completion and submission, you may click the **close** button at the bottom of the page under the list of folders.
  - ii. You will be asked, ‘Would you like to save this document before you close it?’
  - iii. Click the **yes** button

- 2. No action is need in the Additional Information folder.

- 3. Organizations folder
  - a. Click for Organization Lookup and search for all sites at which the research will be conducted.
  - i. The Organization Type field defaults to “Frequently Used in IRB” and will automatically return a list of commonly used organizations.
  - ii. If your organization(s) doesn’t appear in the list, change the Organization Type in the drop-down menu to “select” and use the search fields to enter criteria; click **search**.
    - A. Click on the [ ] under Organization Name to sort the list alphabetically.
    - B. To choose an organization(s), click in the box next to the appropriate name(s) under the Select? Column and click **return selected**.
    - C. If you are still unable to locate at least one organization where your research will be conducted, select Indiana University to enter for the Organizations Tab, and list the other organization(s) on the Sites & Collaborations Questionnaire.
iii. If you are able to find some but not all your Organizations, enter the ones you are able to locate for the Organizations Tab, and list the other organization(s) on the Sites & Collaborations Questionnaire.

iv. To remove an organization, click delete organization under Actions.

4. No action is needed in the Funding Sources folder.

5. Click save or click on Personnel tab (e-doc will automatically save and assign a protocol #, if this is the first save).

6. Make note of the Protocol #, located at the top of the page or on the Status & Dates folder, and enter this on all the forms and study documents (Refer to the Human Subjects Office Website for a list of the required forms for a Non Human Subjects Research Submission).
Personnel Tab

KC IRB Protocol > Personnel Tab

1. The Principal Investigator who was selected in the Protocol tab will be displayed in a folder in the Personnel tab. Click show on the person’s folder, then click show on Person Details tab.
   a. Select Affiliation Type
      1. If the individual is IU an faculty member, staff, or study, or has an IU username, choose IU.
      2. If the individual is not IU an faculty member, staff, or student and does not have an IU username, but is a member of an institution which utilizes the IU IRBs (e.g. IU Health, Wishard/Eskenazi Health, Regenstrief,Roudebush VAMC), choose Affiliated.

2. Lead Unit should automatically populate under the Unit Details section of the Principal Investigator’s section.
   iii. If the individual is not affiliated with IU or an institution which utilizes the IU IRBs (see above), choose Non-Affiliated.
Permissions Tab

KC IRB Protocol > Permissions Tab > Assigned Roles

Study personnel are automatically assigned certain permissions based on the protocol role assigned to them on the Personnel tab. For more information about automatic permissions, please see the Quick Reference Guide – Permissions.

If individuals who are not a part of the study team need to view protocol information, make submissions or request IRB actions, or receive protocol notifications (approvals, etc), they must be designated as a Study Manager/Correspondent on the Permissions tab.
**Permissions Tab**

KC IRB Protocol > Permissions Tab > Users

<table>
<thead>
<tr>
<th>Add:</th>
<th>User Name</th>
<th>Full Name</th>
<th>Unit #</th>
<th>Unit Name</th>
<th>Role</th>
<th>Actions</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>scohair</td>
<td>O’Hair, Scott</td>
<td>IU-RSCH</td>
<td>RESEARCH ADMINISTRATION</td>
<td>Aggregator</td>
<td>edit role</td>
</tr>
</tbody>
</table>

1. In Users section:
   a. If you know the individual’s IU user name, enter it into the box in the **User Name** column. Skip to instruction 2 below.
   b. To search for an individual, click on the **button in the **User Name** column.
      i. Click **Clear**.
      ii. Search using the criteria available; last name or email address returns the best results. If only part of an email address or last name is known, you may enter * as a substitute for unknown letters. For example, if searching Smithwick, you could enter Smith* to return the same results.
      iii. Click **Search**.
      iv. Click the return value link associated with the appropriate person.

2. Click the **drop-down** button under Role and select Study Manager/Correspondent. DO NOT select Viewer, Aggregator, or Protocol Deleter.

3. Click **add**.

**NOTE:** Study contacts must have an IU User ID in order to be listed as a Study Manager/Correspondent. Please review the Quick Reference Guide - Accessing KC IRB for instructions on requesting an IU computing account.

To remove a Study Manager/Correspondent:
1. Select the **delete** button under **Actions** to the right of the **User Name** and **Role**.
2. A question will appear: Are you sure you want to delete **XXX, XXX XXX** from the list of users?
   a. Click **yes**.
Questionnaire Tab

KC IRB Protocol > Questionnaire Tab

No action is required in the Questionnaire tab.
Notes and Attachments Tab

KC IRB Protocol > Notes and Attachments Tab > Protocol Attachment

1. Click on the Notes & Attachments tab.

2. Click show on Protocol Attachments folder to attach the required study documents (Refer to the Human Subjects Office Website for the required form for an Application for Non-Human Subjects Research)
   a. Select an Attachment Type of Other from drop-down list.
   b. Select Complete for Status if the document is the version you want to submit. If additional changes are needed, select Incomplete; note that you will not be able to submit the protocol until all attachments have a status of complete.
c. Enter a **Description**, e.g. Application for Non Human Subjects Research.

d. Other fields which can be completed if needed, though not required for saving, are **Contact Name**, **Email**, **Phone**, and **Comments**.

e. To add an attachment, click **Browse** for **File Name** search.

   i. Locate the file and click **Open** to attach. Note: all commonly used file types should be compatible except for ".msg" (outlook messages)

f. When file returns, click **add**.

3. Once an item is attached, it is listed under **Attached Items**; details can be seen by clicking show/hide buttons.
Notes and Attachments Tab

KC IRB Protocol > Notes and Attachments Tab

4. Click on the **show** button of an attachment to: **view**, **replace**, or **delete**.
   a. To view an attachment, click on **view**.
      i. A popup window will appear; select Save or open to view the file.
   b. To replace an attachment, click on **replace**.
      i. This removes the attachment and you can **Browse** for a new **File Name**.
      ii. Locate the file and click **Open** to attach.
   c. To delete an attachment, click on **delete**.
      i. A question will appear: Are you sure you would like to delete the following attachment: **XXX.XXX**?
      ii. Click **yes** or **no**

5. The number of **Protocol Attachments** is indicated on the folder label in parentheses.
6. To add a **Note**, enter a Note Topic and Note Text.
Notes and Attachments Tab

KC IRB Protocol > Notes and Attachments Tab > Notes

7. Click **add** under **Actions**. This note will be visible to all persons with access to view the protocol.

8. Click **save**

9. To edit or remove a note, click the **edit** or **delete** button under **Actions**. Once a note has been added, it can be **deleted** by persons with the Aggregator role on the protocol up until it is submitted to the IRB. Other personnel can view the notes.

10. The number of **Notes** is indicated on the folder label in parentheses.

11. Click **Protocol Actions** tab (e-doc will automatically save when moving to a new tab).
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.
Protocol Actions Tab

KC IRB Protocol > Protocol Actions Tab > Request an Action > Submit for Review

1. Click **show** on the **Request an Action** folder.
2. Click **show** next to **Submit for Review**.
3. Select **Submission Type** of **Initial Protocol Application** from the drop down list.
4. Select **Submission Review Type** of **IRB Review Not Required**.
5. Select a **Type Qualifier** of **Non-Human Subjects**.
6. Click **submit**.
7. KC IRB will validate some of the information entered (e.g. check for empty fields, required responses, investigator training, etc.) and may 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 errors present, repeat steps above to submit the protocol for review.

8. The following message will be returned: **Document was successfully submitted.**
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.