NEW PROTOCOL - HUMANITARIAN USE DEVICE (HUD) TRAINING GUIDE
About this Document

This document provides:

Instructions for creating and submitting a new humanitarian use device (HUD) protocol.
1. Required Fields for Saving Document folder. Enter:
   a. Protocol Type = Humanitarian Use Device (HUD)
   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, such as Last Name, using an * (e.g., Johnson*)
         2. Click search
         3. Click return value link
   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 > Additional Information

1. Click show on Additional Information folder.
   a. Enter the HDE# in the FDA IND/IDE # field

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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.

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

5. No action is needed in the Participant Types folder.

6. Click save.

7. 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 an HUD protocol).
Personnel Tab

KC IRB Protocol > Personnel Tab > Person Details

1. The Principal Investigator who was selected in the Protocol tab will be displayed in a folder in the Personnel tab.

2. Click show on the person’s folder, then click show on Person Details tab.
   a. Select Affiliation Type
      i. If the individual is an IU faculty member, staff, or study, or has an IU username, choose IU.
      ii. If the individual is not an IU 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.

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

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 \( \text{button} \) 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 \( \text{button} \) 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.
Much of the information for a new Humanitarian Use Device study application will be housed directly in the KC IRB system on the Questionnaire Tab. Questionnaires function as “smart forms,” so as you answer questions additional questions or Questionnaire folders will be displayed based on responses you provide.

Only supporting documents (such as product labeling or the FDA HDE letter) will need to be added to the Notes & Attachments Tab.

1. The required Questionnaire for this study will populate on this tab automatically, based on your answers on the Protocol tab.

2. Complete the questions.

3. Click **update** to save changes. When all required questions have been answered, the individual Questionnaire tabs will change from “(Incomplete)” to “(Complete).”
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 a list of the required forms for an HUD protocol).
   a. Select an **Attachment Type** from drop-down list.
   b. Status will default to **Complete**. If additional changes are needed, and you wish to store a copy here for update at a later time, 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** that will help you identify the document. It is recommended that you include a version date or number within the description. For example, ‘Consent form – healthy controls v.08.19.2013’
Notes and Attachments Tab

KC IRB Protocol > Notes and Attachments Tab > Protocol Attachments

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. Repeat above steps for each attachment.

4. Upload Zip documents
   Several attachments can be uploaded with one click. Use the “Upload Zip” button which will 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.

5. 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 > Protocol Attachments

6. 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

7. The number of Protocol Attachments is indicated on the folder label in parentheses.

8. To add a Note, enter a Note Topic and Note Text.
   a. Click add under Actions. This note will be visible to all persons with access to view the protocol.
   b. Click save
   c. 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.
   d. The number of Notes 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.
1. Click on the Protocol Actions tab.

2. Click *show* on the **Request an Action** folder.

3. Click *show* next to **Submit for Review**.

4. Select **Submission Type** of **Initial Protocol Application** from the drop down list.

5. Select **Submission Review Type** of **Full Board**.

6. Do not select a **Type Qualifier**.

7. Click **submit**
Protocol Actions Tab

KC IRB Protocol > Protocol Actions Tab > Data Validation

8. 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.

9. Once there are no validation errors present, repeat steps above to submit the protocol for review.
   - 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.