Creating a Study in eCompliance

1. Go to ecompliance.ku.edu and log in using your KU ID and password. If you are having issues logging in to the system, contact HRPP via email.

2. Once logged in, the system will default you to the inbox. Click the “Create New Study” button in order to get started.
Human Research Protection Program -- KU-Lawrence eCompliance Guide

3. a. **Question 1 & 2:** Type in the title of your study. The “Short title” can either be the same, or if you have a long study, you have the option of shortening this title for convenience.

   b. **Question 3:** Enter in a brief description of the study.

   **Note:** All fields with asterisk are required—please make sure these are filled out completely.

4. **Question 4:** Enter the principal investigator. This will default to the person who is creating the study. If you want to change the PI, click the three dots and a list of every individual and KU will pop up. You can search for the individual and click “OK” when finished.

5. **Question 5:** If the principal investigator has any financial interest in this study, you will want to mark “yes” here. Otherwise, click “no” and continue.
6. **Question 6:** Choose which campus you wish to review. For Lawrence campus, click “KU Lawrence.”

   ![Which IRB should oversee this study?](image)

7. **Question 7:** Indicate if there will be an external IRB involved in this study.

   *Note: ONLY click this button if another institution has received IRB approval, you have had a conversation with HRPP, and we have agreed to sign an IRB Authorization Agreement with another institution.*

   ![Will an external IRB act as the IRB of record for this study?](image)

8. **Question 8:** This is where you can attach the Human Research Protocol. **This document is required for all new studies.** Attach the document by clicking “Choose File” and finding the saved application on your computer. You also can assign it a name and number version, if you so choose. Click “OK” and the application should be downloaded into the system.

   ![Attach the protocol:](image)
9. Once you are finished with this page, click “Continue.”

8. 

   * Attach the protocol:

   ![Protocol Attachment Interface]

   - Category: IRB Protocol
   - Date Modified: 7/26/2017
   - Document History

   Update

10. The next page is where you include any funding sources you have on this project. You can add these by clicking “Add.” If you do not have a funding source, you can click “Continue.”

   **Note:** If your funding source does not show up, contact [HRPP](mailto:hrp@ku.edu) to have it added.

   ![Funding Sources Interface]
11. This will make a window pop up. You can find the organization by searching by title in the “Funding Organization” box, or by clicking the ... right beside the box. You also have the option to add in funding IDs and Grad IDs along with uploading any applications. Once you are complete, click “OK.”

*Note: Certain government agencies will show up by searching “US Dept...”*
12. Once you have added in your funding sources, you can click “Continue.”

**Funding Sources**

1. Identify each organization supplying funding for the study:
   - Dept of Defense

13. The next page is the Study Team Members page. Anyone who is involved in the following procedures should be added to this page:
   
   a. Obtaining consent from participants for research purposes
   
   b. Interacting/Intervening with participants for research purposes
   
   c. Has access to identifiable data for research purposes
   
   KU Faculty, staff, and graduate students are automatically in the system. Click “Add” to search for their names. **Undergraduates are not automatically added into the system.** To add them, call HRPP (785-864-7385) with their 7-digit KU ID.

   *If you have someone on your study who is not associated with the University of Kansas, please contact HRPP to find out what is needed.*

**Study Team Members**

1. Identify each additional person involved in the design, conduct, or reporting of the research:

<table>
<thead>
<tr>
<th>Name</th>
<th>Roles</th>
<th>Financial Interest</th>
<th>Involved in Consent</th>
<th>E-mail</th>
<th>Phone</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

   There are no items to display

   By clicking “Select” you can search by first and last name. Once you have found the individual, click their role in research. Indicate if the member is involved in the consent process and if they have a financial interest, and when finished, click “OK.” If you have multiple ones, you can click “OK, add another.”

   **Note: All students who submit will need to add their faculty advisor to the study team page.**
14. Once you are finished, click “continue.” The next page you will need to answer whether your research is occurring at external sites, whether your study involves a drug, or whether it involves a device.

If your research involves none of these options, click “No” and click “Continue.” If you click “yes” to any of these options, a new page will open and you will have new questions to answer about your study scope.
15. External site should only be checked if your research is taking place off-site at another institution, school, company, or university/college, in which the site specifically is significant to your research goals/hypothesis. Do not click this button if your interviews are taking place in public areas (e.g. coffee shops) for the participant’s convenience, if the site is not related to your research goals whatsoever.

16. a. If you answer “yes” to Study Scope Question 2 (use of approved drugs), you will be prompted to enter in the drug, food, and supplement information.
   
b. Question 3 requires you to add information about devices that will be used.
17. Once these questions have been answered, click “Continue.” The next page is where you upload any consent and recruitment materials. Click “Add” and click “Choose File” in order to find your appropriate consent documents.
18. Once you are finished uploading, click “continue.” The next page will be any additional documents that did not fit into the other categories. This can include survey/interview questions, assent procedures, test/assessments, debriefing statements, external site approval letter, Environmental Health & Safety (EHS) approval, HIPAA documents, etc.
19. Click “continue,” and this will take you to the final page. Click “Finish” when your application is complete. Pay attention to point 2 on this page—you will need to click submit on the next page.

20. eCompliance will then take you to your study home page.

In order to submit it for review, you will need to click “Submit” in the left side of the screen. **Students who are submitting will need to submit an ancillary review to their faculty advisor before submitting their project for review. Directions for this process can be found on the IRB website.**

**Note:** If you are not the PI of the study you have created, click the “Notify PI” button. You can then enter text to the PI, which will be sent to their KU email address.
21. Once you are ready, click “submit.” Click “Ok” on the next page. This will prompt you to enter in your KU ID and password.
22. Your study has now been submitted to the IRB! You can check on your progress of your application any time by logging into the system, and following the “Access Your Studies” guide. The flow-chart at the top of the page will show you the progress your application is making—along with the History that will show you any clarifications that HRPP is requesting. For more information on how to respond to clarifications, please see our “Responding to Clarifications” guidance. If you have additional concerns or questions, contact HRPP via email or phone.
Looking for something else? There is more information available on the HRPP website:

**Quickstart**

- Accessing a Study
- Continuing Review
- Modification
- Study Team Modification
- Changing Principle Investigator
- Adding Funding
- Creating an External IRB Study
- Responding to Clarifications
- Closing a Study

**Guides**

- Student Ancillary Review Guide
- Faculty Supervisor Ancillary Review Guide