Before you start, determine if your project is a Single-Site or Multi-Site Study.

Note: A project is determined single/multi-site based on **who is conducting the research procedures**, not the amount of research locations. You can have a single-site project that has multiple research locations.

**Single-Site Projects:** Only KU-Lawrence researchers (personnel or investigators under an Individual Investigator Agreement) are conducting the research procedures.

Example: KU-Lawrence personnel **only** are conducting interviews at 1 or more research location.

**If your study is a single-site project, please follow this link to view the guide for Creating a Single-Site Study in eCompliance.**

**Multi-Site Projects:** KU-Lawrence researchers and researchers from another institution will both be conducting research procedures.

Example: KU-Lawrence personnel are conducting interviews. University of Missouri collaborators will also be conducting interviews.

If you have questions, email irb@ku.edu or call (785) 864-7429 ext. 2.

**Creating a Multi-Site 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.

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.”
Note: Use this chart to for assistance with questions 7-9. If you need to set up a IRB Authorization Agreement (e.g. reliance agreement) with another institution, please email irb@ku.edu.

<table>
<thead>
<tr>
<th>7. Will an external IRB act as the IRB of record for this study?</th>
<th>8. What kind of study is this?</th>
<th>9. Will your IRB act as the single IRB of record for other participating sites?</th>
<th>Types of studies</th>
<th>More Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td>Multi-site</td>
<td>Yes</td>
<td>Where KU-Lawrence IRB is anticipated to be the reviewing IRB for other relying academic institutions or other sites engaged in human subjects research, and where an MOU or an IRB Authorization Agreement (reliance agreement) has been (or will be) signed between the parties.</td>
<td>• KU-Lawrence will be serving as the IRB of record for a study conducted by multiple institutions (with IRBs), in which one or more institution will rely on the KU-Lawrence IRB review. • KU/KUMC collaborative projects</td>
</tr>
<tr>
<td>No</td>
<td>Multi-site</td>
<td>No</td>
<td>Where KU-Lawrence is involved in a study in which multiple academic institutions will be conducting study activities, but the KU-Lawrence IRB will not and never will be responsible for other sites as an IRB of record.</td>
<td>• Collaborator’s institution’s IRBs will be reviewing their portion of the project, and the KU IRB is only reviewing and approving the work conducted by KU personnel and/or affiliates.</td>
</tr>
</tbody>
</table>

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.*

8. **Question 8:** Indicate whether the study is a Single-site or Multi-site study. If you think your study is a single-site study, refer to the single-site study guide.

8. **What kind of study is this? (Once this selection is saved, it cannot be changed.)**
   - Single-site study (One institution conducting study activities)
   - Multi-site study (Multiple institutions conducting study activities)
   
   Clear
9. Question 9: This question should have appeared after the selection of multi-site study. This question is referring to the IRB of record for your study. If your IRB will act as the IRB of record, select yes.

9. * Will your IRB act as the single IRB of record for other participating sites? (Once this selection is saved, it cannot be changed.)
   - Yes
   - No
   - Clear

10. Question 10: 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.

11. Once you are finished with this page, click “Continue.”
12. 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 to have it added.*

13. 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...”*
14. Once you have added in your funding sources, you can click “Continue.”
15. 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.

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.
16. 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.
17. Other research locations 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. Here you can add each external research location and their contact information.

**Research Locations**

1. **Identify other research locations where the investigator will conduct or oversee the research:**

<table>
<thead>
<tr>
<th>Location</th>
<th>Contact</th>
<th>Phone</th>
<th>Email</th>
</tr>
</thead>
</table>

There are no items to display

**Add Research Location**

**Add Research Location Information**

1. **Select the research location:**

   If you cannot find the research location in the list above, enter its information here:

   a. Location name:

   b. Location address:
      - Address line 1
      - Address line 2
      - Address line 3
      - City
      - State or province
      - Postal code
      - Country

   c. Contact name:

   d. Contact phone:

   e. Contact e-mail:
18. 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.

Drugs

1. * List all drugs, biologics, foods, and dietary supplements to be used in the study:
   - Add
   - Generic Name | Brand Name | Attachment Name
   - There are no items to display

2. * Will the study be conducted under any IND numbers? *
   - Yes
   - No
   - Clear
   - If so, identify each IND:
     - Add
     - IND Number | IND Holder | Other Holder
     - There are no items to display

3. Attach files: (such as IND or other information that was not attached for a specific drug)
   - Add
   - Document | Category | Date Modified | Document History
   - There are no items to display

Devices

1. * Select each device the study will use as an HUD or evaluate for safety or effectiveness:
   - Add
   - Device | Humanitarian Use Device | Attachment Name
   - There are no items to display

2. * Device exemptions applicable to this study: *
   - IDE number
   - HDE number
   - Claim of abbreviated IDE (nonsignificant risk device)
   - Exempt from IDE requirements
   - Clear

3. If applicable, identify each IDE and HDE number:
   - Add
   - IDE / HDE Number | IDE / HDE Holder | Other Holder
   - There are no items to display

4. Attach files: (such as IDE, HDE, or other information that was not attached for a specific device)
   - Add
   - Document | Category | Date Modified | Document History
   - There are no items to display
19. Once these questions have been answered, click “continue.” The next page is where you can upload any local site documents. **Local site-specific documents may include local versions of consent forms or recruitment materials. Some documents and consent forms will be applied to the multi-site study as a whole. Others may be specific to your institution.**

On this page, only include the documents that are specific to your institution. Click “Add” and click “Choose File” in order to find your appropriate consent forms, recruitment materials, and other attachments related to the site such as survey/interview questions, assent procedures, tests/assessments, debriefing statements, HIPAA documents, etc.

**Local Site Documents**

1. **Consent forms**: (include an HHS-approved sample consent document, if applicable)

<table>
<thead>
<tr>
<th>Document</th>
<th>Category</th>
<th>Date Modified</th>
<th>Document History</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
   
   There are no items to display.

2. **Recruitment materials**: (add all material to be seen or heard by subjects, including ads)

<table>
<thead>
<tr>
<th>Document</th>
<th>Category</th>
<th>Date Modified</th>
<th>Document History</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
   
   There are no items to display.

3. **Other attachments:**

<table>
<thead>
<tr>
<th>Document</th>
<th>Category</th>
<th>Date Modified</th>
<th>Document History</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
   
   There are no items to display.

**Suggested attachments:**

- Completed checklist of meeting Department of Energy requirements, if applicable
- Other site-related documents not attached on previous forms
20. The next page is for study-related documents that are not specific to the site. Here you can upload consent and recruitment templates as well as other attachments related to the study such as survey/interview questions, assent procedures, tests/assessments, debriefing statements, HIPAA documents, etc.

Study-Related Documents

1. Consent form templates: (include an HHS-approved sample consent document, if applicable)
   - Document
   - Category
   - Date Modified
   - Document History
   There are no items to display

2. Recruitment material templates: (add templates for all material to be seen or heard by subjects, including ads)
   - Document
   - Category
   - Date Modified
   - Document History
   There are no items to display

3. Other attachments:
   - Document
   - Category
   - Date Modified
   - Document History
   There are no items to display

Suggested attachments:
- Completed checklist of meeting Department of Energy requirements, if applicable
- Other study-related documents not attached on previous forms

21. 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.

Final Page

You have reached the end of the IRB submission form. Read the next steps carefully:

1. Click Finish to exit the form.

2. Important! To send the submission for review, the principal investigator must click Submit on the next page.

22. 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.**

Human Research Protection Program
irb@ku.edu
785-864-7429 ext. 1
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.

23. Once you are ready, click “submit.” Click “Ok” on the next page. This will prompt you to enter in your KU ID and password.
24. 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.
25. Now that your study has been submitted you can add participating sites. On the left hand side under Next Steps, click Add Participating Sites to add a site and PI to your study. If you cannot find your site or principal investigator in the system, contact irb@ku.edu for assistance.

**Next Steps**

- View Study
- Printer Version
- View Differences
- Create Modification/CR
- Report New Information
- **Add Participating Sites**
- Assign Primary Contact
- Manage Guest List
- Add Comment
- Copy Submission

**Add Participating Sites**

1. **Add participating sites:**

<table>
<thead>
<tr>
<th>Institutional Profile</th>
<th>Principal Investigator</th>
</tr>
</thead>
</table>

There are no items to display

[Add]
Looking for something else? There is more information available on the HRPP website:

Quickstart

✓ Accessing a Study
✓ Creating a Single-Site Study in eCompliance
✓ 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