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

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

*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.

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

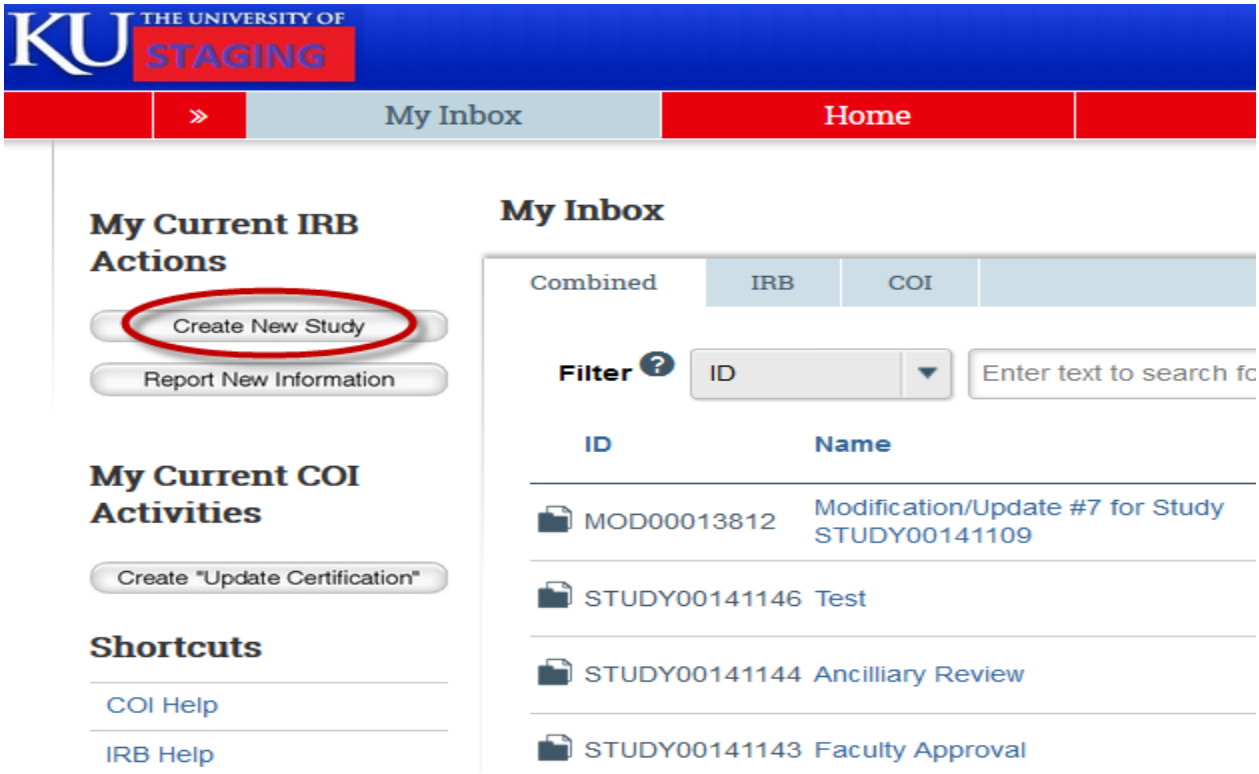
Example: KU-Lawrence personnel are conducting interviews. University of Missouri collaborators will also be conducting interviews.

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

Creating a Single-Site Study in eCompliance

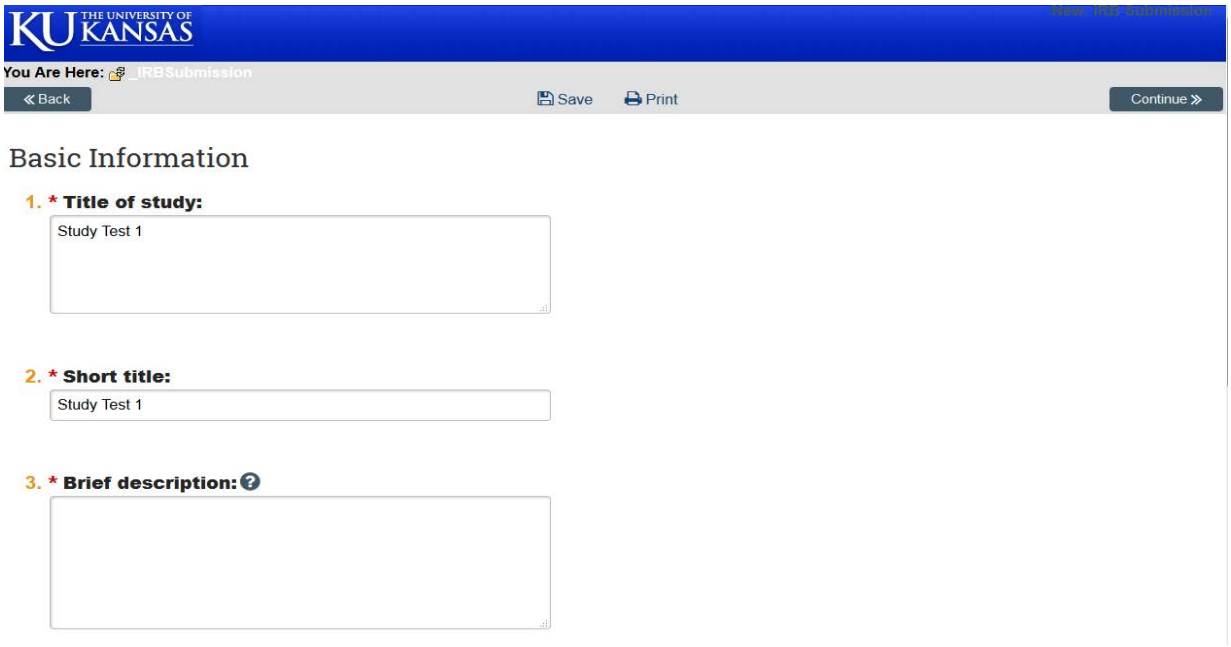
1. Go to ecompliance.ku.edu and log in using your KU ID and password. If you are having issues logging in to the system, contact HRPP via email.

2. Once logged in, the system will default you to the inbox. Click the "Create New Study" button in order to get started.

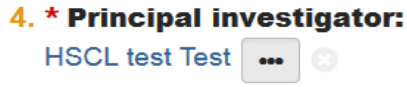


3. a. **Question 1 & 2:** Type in the title of your study.
   The "Short title" can either be the same, or if you have a long study, you have the option of shortening this title for convenience.
   b. **Question 3:** Enter in a brief description of the study.

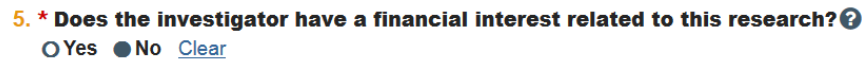
Note: All fields with asterisk are required—please make sure these are filled out completely.



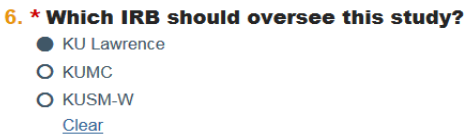
4. **Question 4**: Enter the principal investigator. This will default to the person who is creating the study. If you want to change the PI, click the three dots and a list of every individual and KU will pop up. You can search for the individual and click "OK" when finished.



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."



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.

7. * **Will an external IRB act as the IRB of record for this study?**
   ○ Yes ● No Clear

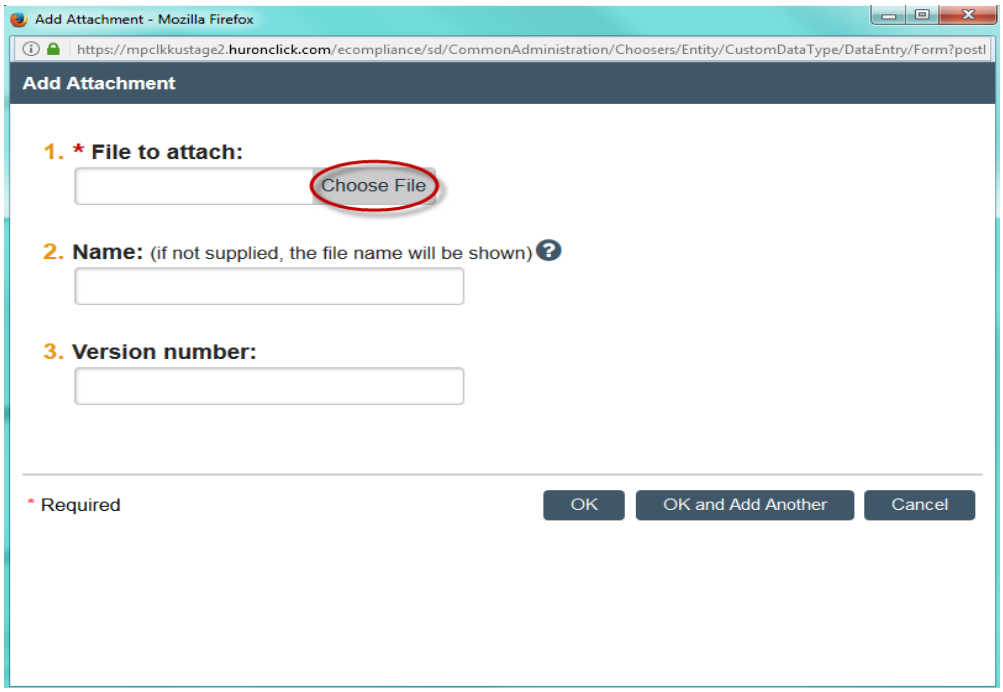
8. Question 8: Indicate whether the study is a Single-site or Multi-site study. If you think your study is a multi-site study, refer to the multi-site study guide.

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 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.

9. * **Attach the protocol:**

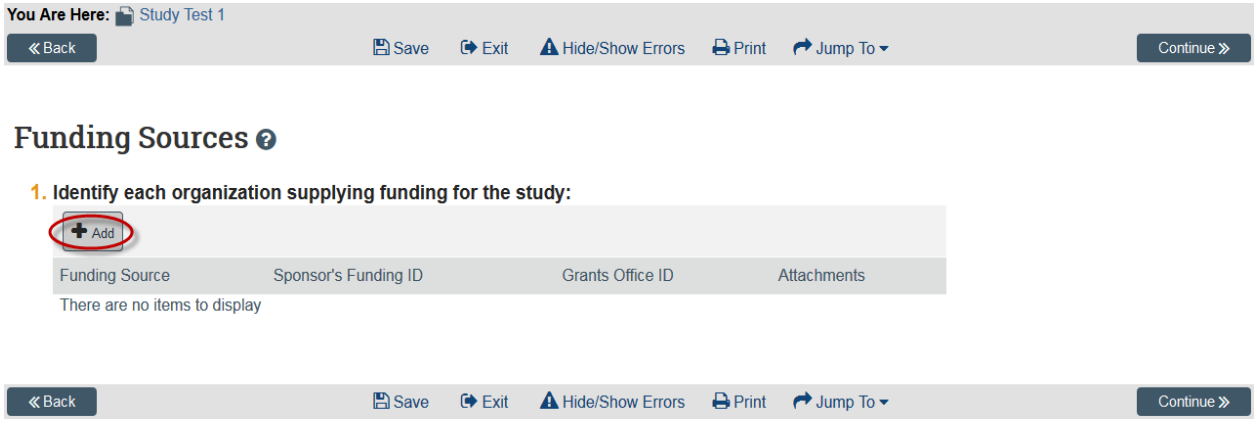
Add			
Document	Category	Date Modified	Document History
There are no items to display			



10. Once you are finished with this page, click "Continue."

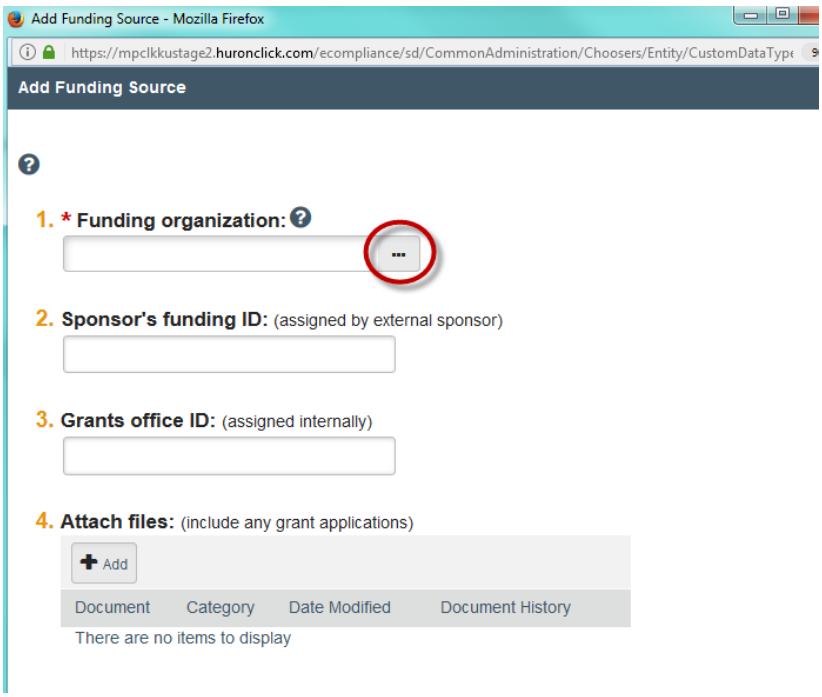
11. The next page is where you include any funding sources you have on this project. You can add these by clicking "Add." If you do not have a funding source, you can click "Continue."

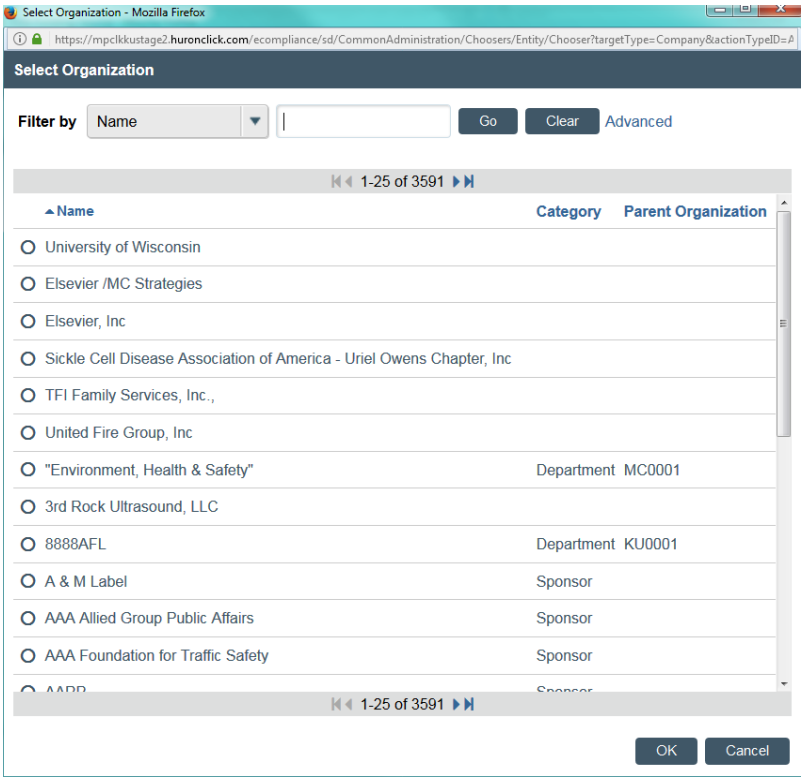
Note: If your funding source does not show up, contact HRPP to have it added.



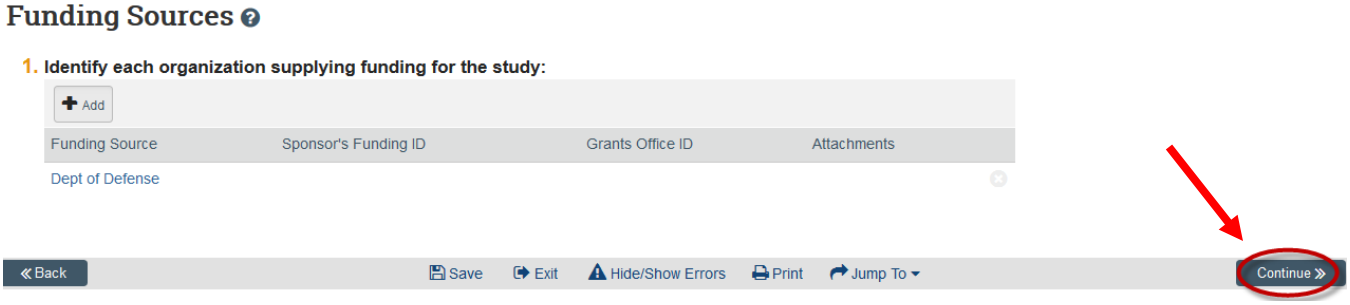
12. This will make a window pop up. You can find the organization by searching by title in the "Funding Organization" box, or by clicking the … right beside the box. You also have the option to add in funding IDs and Grad IDs along with uploading any applications. Once you are complete, click "OK."

Note: Certain government agencies will show up by searching "US Dept…"





13. Once you have added in your funding sources, you can click "Continue."



14. The next page is the Study Team Members page. Anyone who is involved in the following procedures should be added to this page:

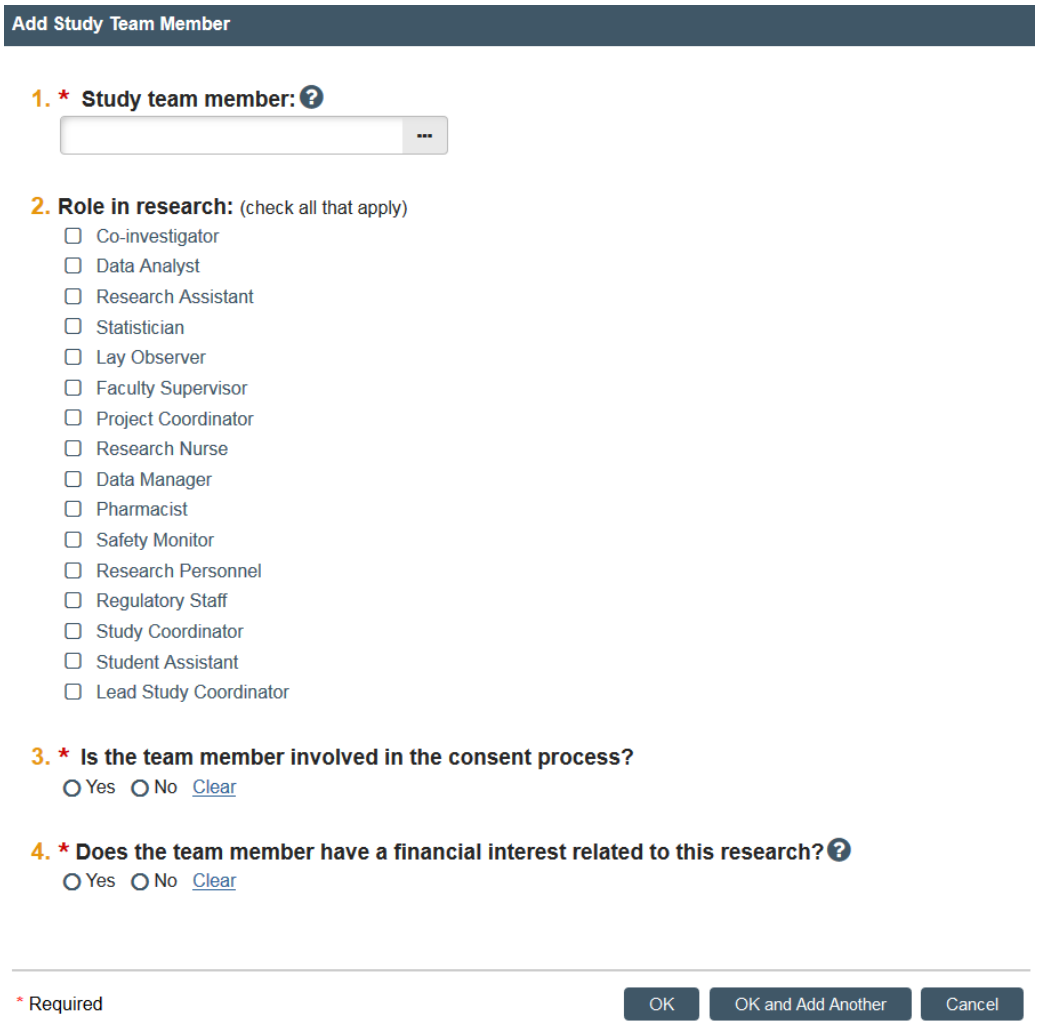
    a. Obtaining consent from participants for research purposes
    b. Interacting/Intervening with participants for research purposes
    c. Has access to identifiable data for research purposes

    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.

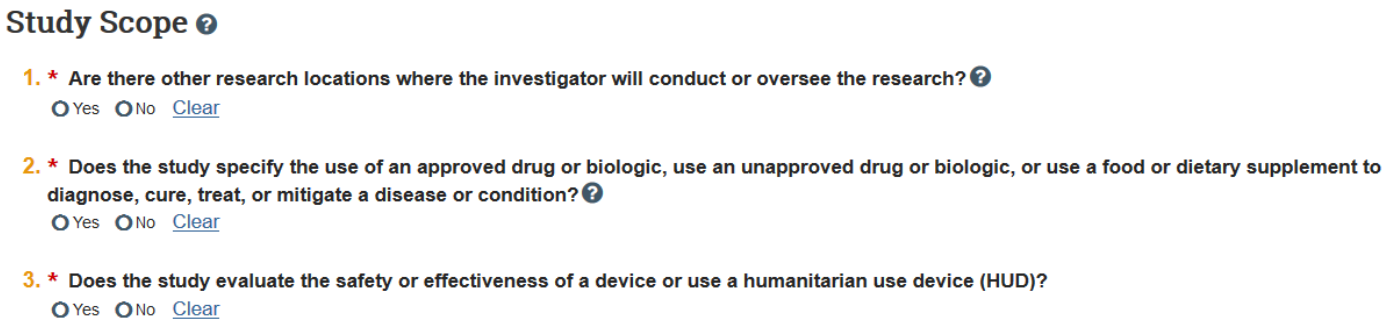
By clicking "Select" you can search by first and last name. Once you have found the individual, click their role in research. Indicate if the member is involved in the consent process and if they have a financial interest, and when finished, click "OK." If you have multiple ones, you can click "OK, add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

Note: All students who submit will need to add their faculty advisor to the study team page.

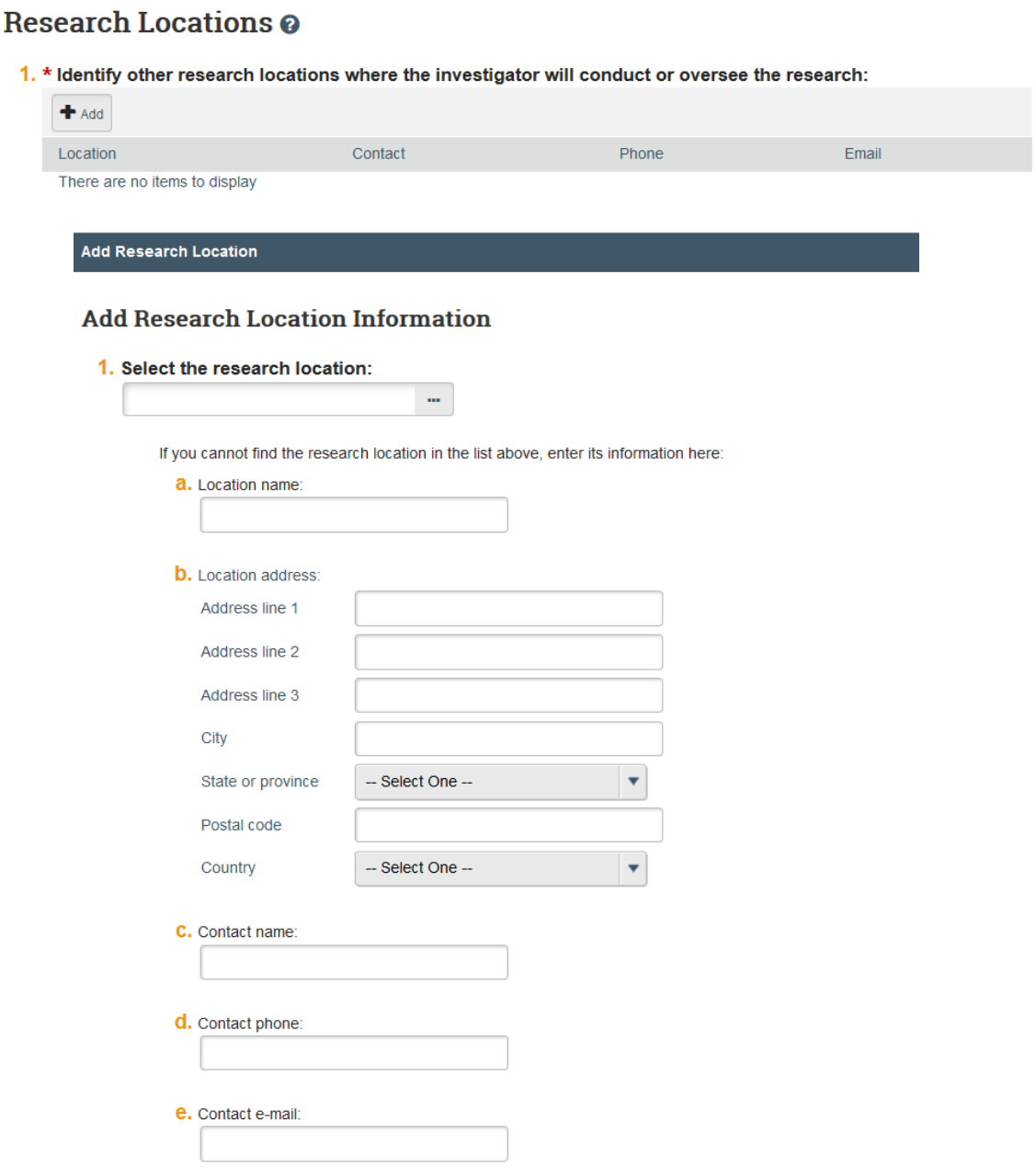


15. Once you are finished, click “continue.” The next page you will need to answer whether your research involves external research locations, drugs, or devices.

    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.



16. **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 which would make your study a multi-site study.** 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. If you don't see your site or PI, contact KU IRB.



17. 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

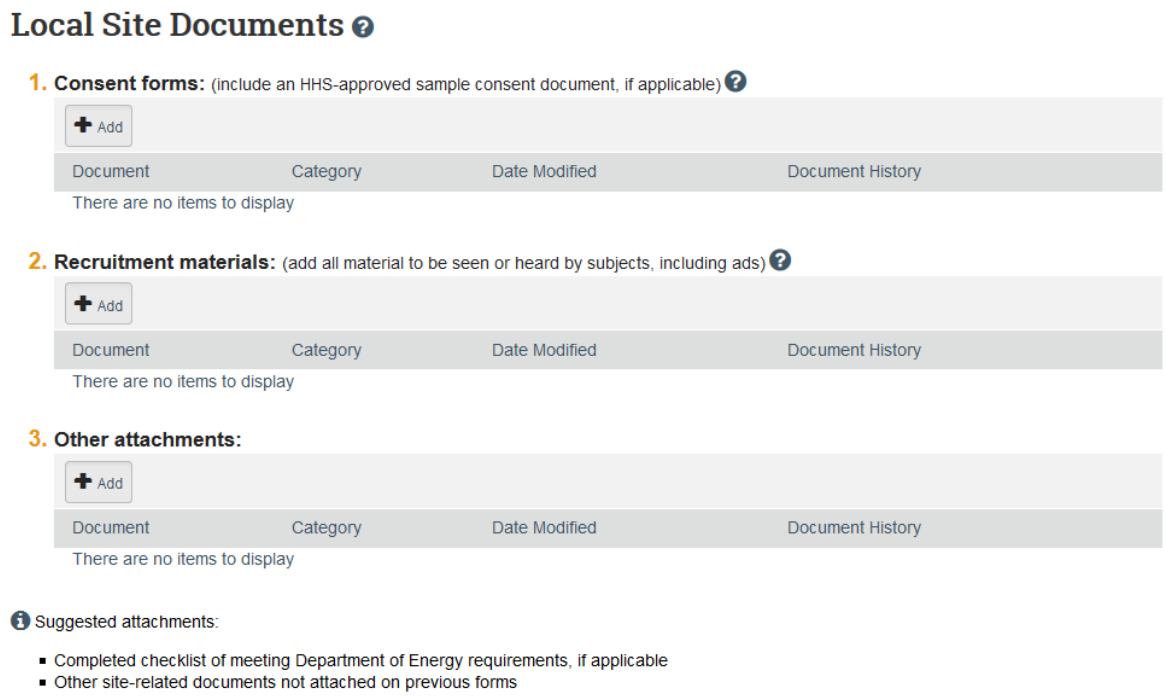
IDE / HDE Number	IDE/ HDE Holder	Other Holder
There are no items to display		

4. **Attach files:** (such as IDE, HDE, or other information that was not attached for a specific device)

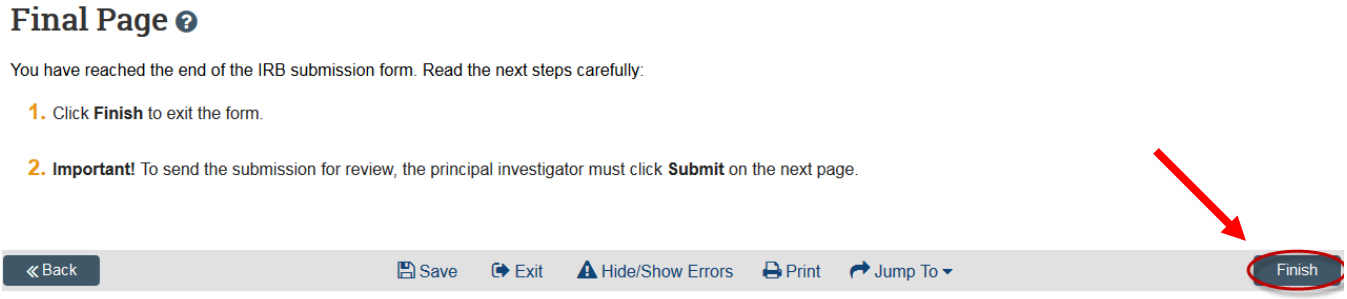
Add

Document	Category	Date Modified	Document History
There are no items to display			

18. Once these questions have been answered, click "Continue." The next page is where you upload any local site documents. Local site-specific documents may include local versions of consent forms or recruitment materials. Click "Add" and click "Choose File" in order to find your appropriate consent forms, recruitment materials, and other attachments such as survey/interview questions, assent procedures, tests/assessments, debriefing statements, HIPAA documents, etc.



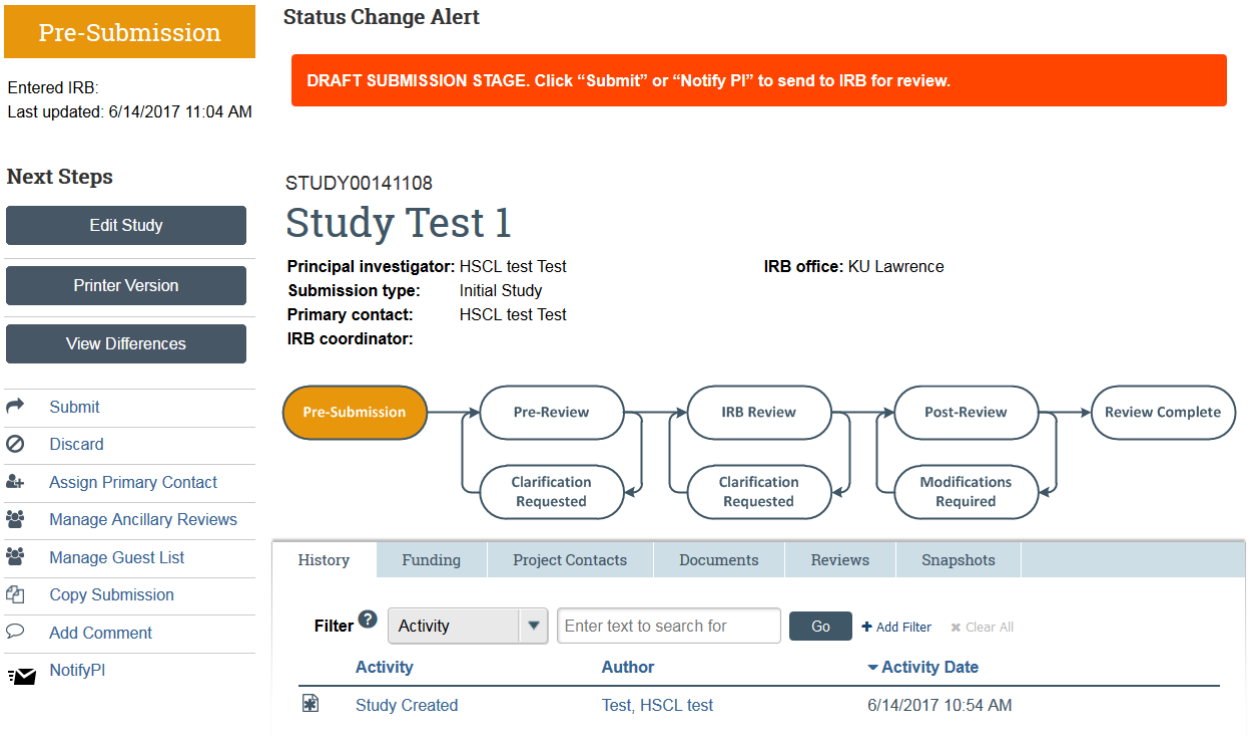
19. Click "continue," and this will take you to the final page. Click "Finish" when your application is complete. Pay attention to point 2 on this page—you will need to click submit on the next page.



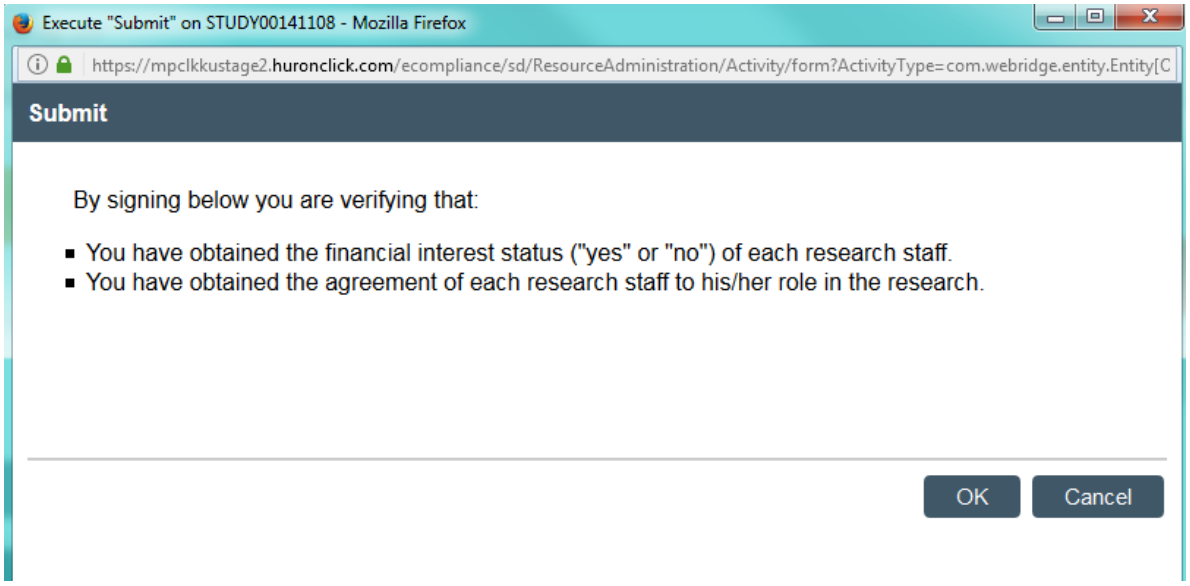
20. eCompliance will then take you to your study home page.
    In order to submit it for review, you will need to click **"Submit"** in the left side of the screen.

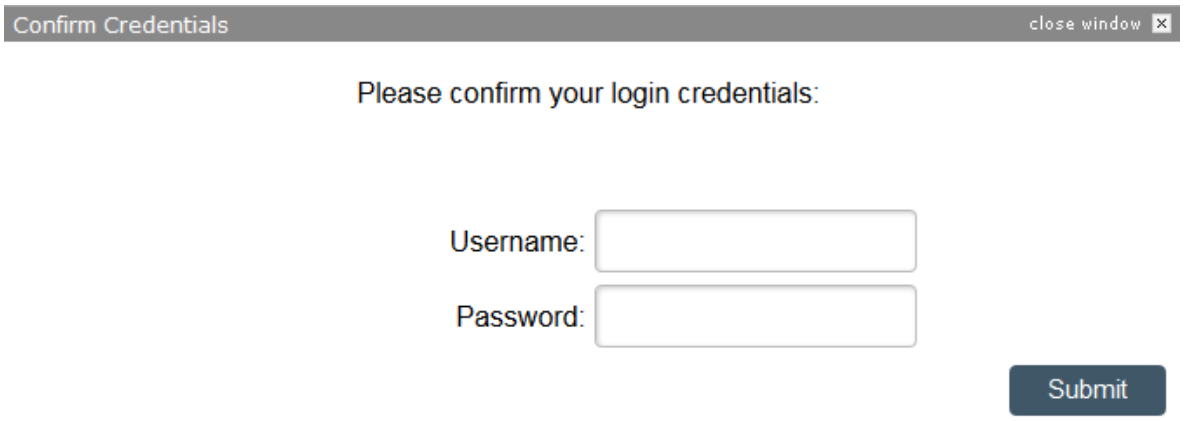
Students who are submitting will need to submit an ancillary review to their faculty advisor before submitting their project for review. Directions for this process can be found on the IRB website.

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.

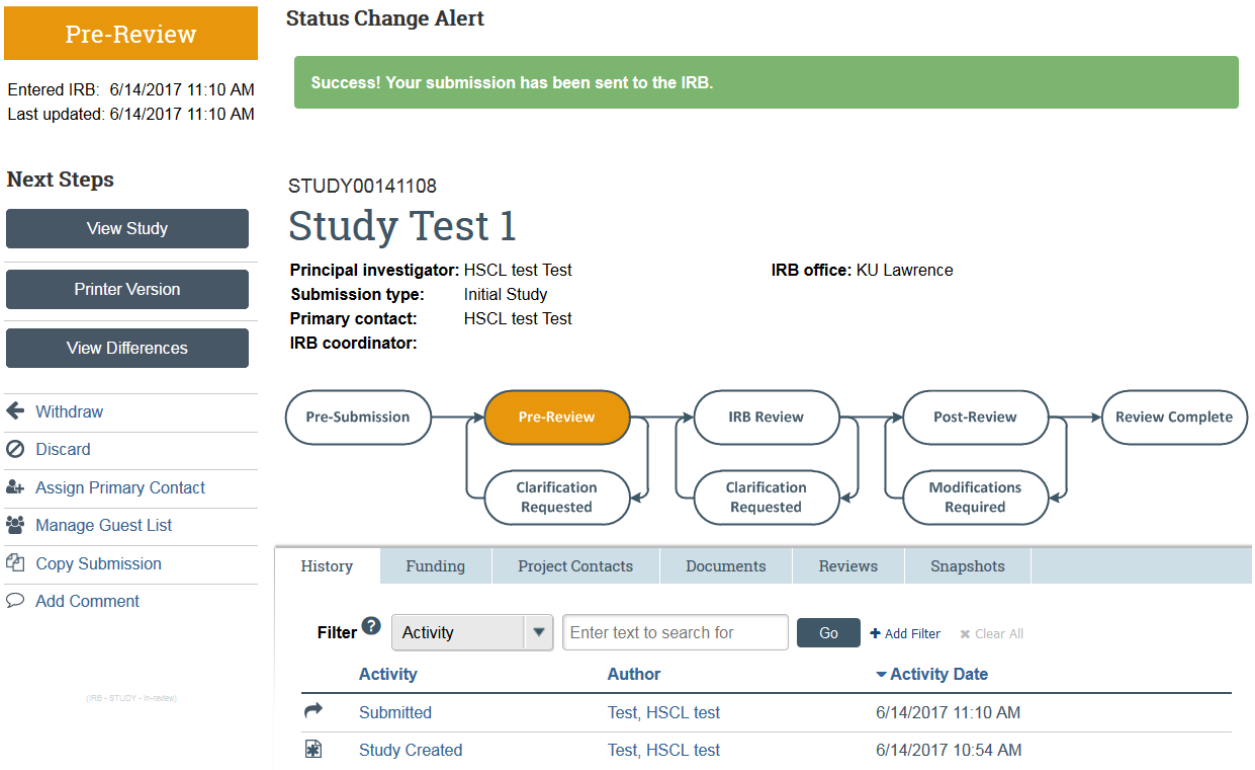


21. Once you are ready, click "submit." Click "Ok" on the next page. This will prompt you to enter in your KU ID and password.





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

- ✓ Creating a Multi-Site Study in eCompliance
- ✓ 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