

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

If you have questions, email [irb@ku.edu](mailto: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](http://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](#).

The screenshot shows the homepage of the KU eCompliance system. At the top left is the KU logo with the text 'THE UNIVERSITY OF KANSAS'. A navigation bar contains a 'Home' link. The main content area is divided into three columns. The left column has 'My Current Actions' and 'Shortcuts' with a link to 'IRB Help'. The center column features the title 'eCompliance Online System for all KU Campuses' followed by 'Conflict of Interest Reporting and Management and Human Subjects Research Protocol Submissions, IRB Review and Document Management'. Below this is a list of three action items: 'View your eCompliance Inbox for links to your action items regarding conflict of interest or human subjects research.', 'Submit an Update to self-report changes in your Conflict of Interest Certification.', and 'Submit materials to a Human Subjects Research Office on your campus'. The right column has a 'Login' section with a 'Click here to login with a specific campus id' link, a 'Login as' label, and input fields for 'User Name' and 'Password'. There is a 'Login' button and a 'Remember me' checkbox. A note below the login fields states: 'After signing into this site, you are bound by the terms and conditions set forth when you received your account.' At the bottom, there is contact information for the eCompliance system, including 'Conflict of Interest and Human Subjects Research', 'KU Lawrence and Edwards campuses', 'KU Medical Center, Kansas City', and 'KU School of Medicine, Wichita', along with a link to 'Contact Information for each Campus'.

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

The screenshot shows the KU STAGING Human Research Protection Program interface. The top navigation bar includes 'My Inbox' and 'Home'. The left sidebar has sections for 'My Current IRB Actions' (with 'Create New Study' circled in red), 'My Current COI Activities', and 'Shortcuts'. The main 'My Inbox' area shows a table of study entries with columns for ID and Name.

ID	Name
MOD00013812	Modification/Update #7 for Study STUDY00141109
STUDY00141146	Test
STUDY00141144	Ancilliary Review
STUDY00141143	Faculty Approval

- 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.*
  - 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.**

The screenshot shows the 'Basic Information' section of an IRB submission form. The header includes the KU logo and navigation options like 'Back', 'Save', 'Print', and 'Continue'. The form contains three numbered questions:

- 1. \* Title of study:** A text box containing 'Study Test 1'.
- 2. \* Short title:** A text box containing 'Study Test 1'.
- 3. \* Brief description: ?** An empty text box.

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.

**4. \* Principal investigator:**

HSCL test Test

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.

**5. \* Does the investigator have a financial interest related to this research? ?**

Yes  No [Clear](#)

6. **Question 6:** Choose which campus you wish to review. For Lawrence campus, click “KU Lawrence.”

**6. \* Which IRB should oversee this study?**

KU Lawrence  
 KUMC  
 KUSM-W  
[Clear](#)

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:

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

1. \* File to attach:  Choose File

2. Name: (if not supplied, the file name will be shown) ?

3. Version number:

\* Required

OK OK and Add Another Cancel

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

9. \* Attach the protocol:

Document	Category	Date Modified	Document History
<input type="checkbox"/> Update HSQL New Submission Form 8.18.14.pdf(0.01)	IRB Protocol	1/10/2018	History

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.**

You Are Here: [Study Test 1](#)

« Back Save Exit Hide/Show Errors Print Jump To Continue »

### Funding Sources ?

1. Identify each organization supplying funding for the study:

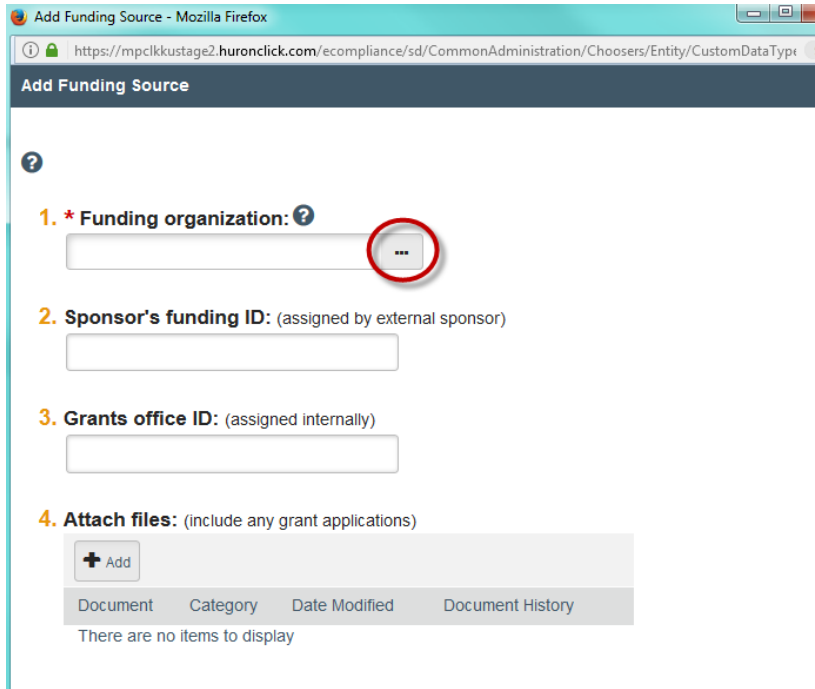
Funding Source	Sponsor's Funding ID	Grants Office ID	Attachments
There are no items to display			

« Back Save Exit Hide/Show Errors Print Jump To Continue »

**Human Research Protection Program -- KU-Lawrence eCompliance Guide**

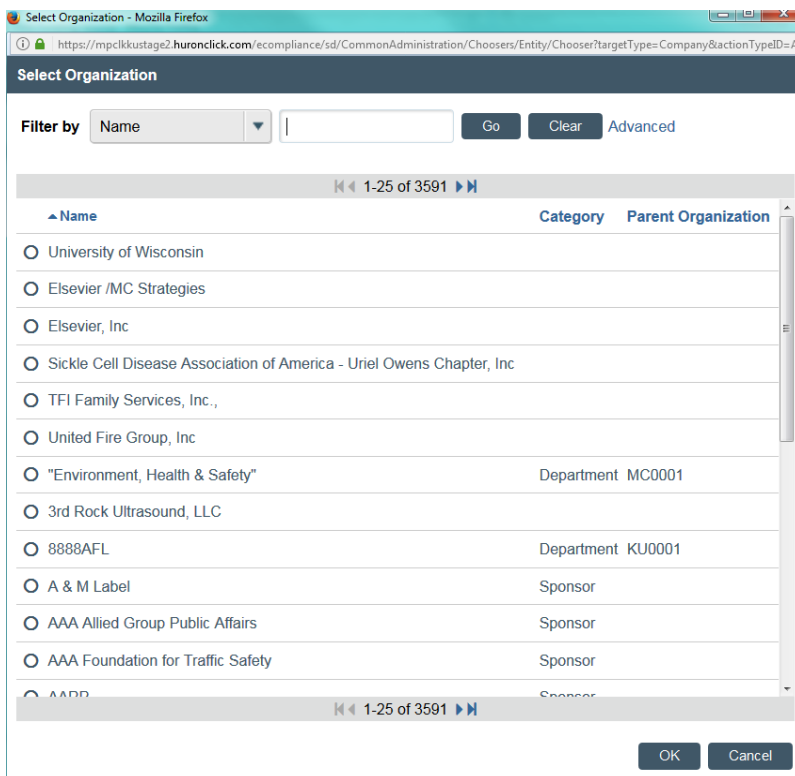
12. This will make a window pop up. You can find the organization by searching by title in the “Funding Organization” box, or by clicking the ... right beside the box. You also have the option to add in funding IDs and Grad IDs along with uploading any applications. Once you are complete, click “OK.”

**Note: Certain government agencies will show up by searching “US Dept...”**



The screenshot shows a web browser window titled "Add Funding Source - Mozilla Firefox". The address bar shows the URL: <https://mpclkkustage2.huronclick.com/ecompliance/sd/CommonAdministration/Choosers/Entity/CustomDataTyp>. The page title is "Add Funding Source". There is a help icon (?) at the top left. The form contains four numbered steps:

- \* Funding organization:** A text input field with a red circle around the "..." dropdown menu.
- Sponsor's funding ID:** (assigned by external sponsor) with an empty text input field.
- Grants office ID:** (assigned internally) with an empty text input field.
- Attach files:** (include any grant applications) with an "+ Add" button and a table header: Document, Category, Date Modified, Document History. Below the header, it says "There are no items to display".



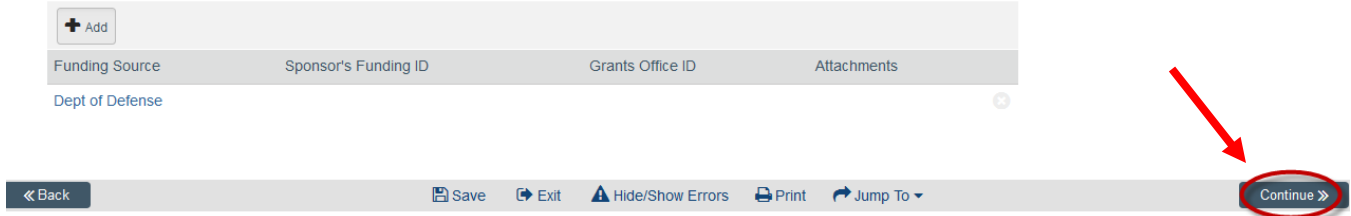
The screenshot shows a "Select Organization" dialog box. At the top, it says "Select Organization". Below that is a "Filter by" section with a dropdown menu set to "Name", an empty search input field, and "Go" and "Clear" buttons. There is also an "Advanced" link. Below the filter section is a table with columns "Name", "Category", and "Parent Organization". The table shows a list of organizations with radio buttons next to each name. At the bottom of the dialog are "OK" and "Cancel" buttons.

Name	Category	Parent Organization
<input type="radio"/> University of Wisconsin		
<input type="radio"/> Elsevier /MC Strategies		
<input type="radio"/> Elsevier, Inc		
<input type="radio"/> Sickle Cell Disease Association of America - Uriel Owens Chapter, Inc		
<input type="radio"/> TFI Family Services, Inc.,		
<input type="radio"/> United Fire Group, Inc		
<input type="radio"/> "Environment, Health & Safety"	Department	MC0001
<input type="radio"/> 3rd Rock Ultrasound, LLC		
<input type="radio"/> 8888AFL	Department	KU0001
<input type="radio"/> A & M Label	Sponsor	
<input type="radio"/> AAA Allied Group Public Affairs	Sponsor	
<input type="radio"/> AAA Foundation for Traffic Safety	Sponsor	
<input type="radio"/> AAPP	Sponsor	

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

### Funding Sources

1. Identify each organization supplying funding for the study:



Funding Source	Sponsor's Funding ID	Grants Office ID	Attachments
Dept of Defense			

<< Back   Save   Exit   Hide/Show Errors   Print   Jump To   **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:

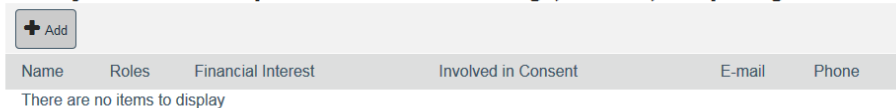
- a. Obtaining consent from participants for research purposes
- b. Interacting/Intervening with participants for research purposes
- c. Has access to identifiable data for research purposes

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.***

### Study Team Members

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



Name	Roles	Financial Interest	Involved in Consent	E-mail	Phone
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.***

Add Study Team Member

1. \* Study team member: ?

2. Role in research: (check all that apply)

- Co-investigator
- Data Analyst
- Research Assistant
- Statistician
- Lay Observer
- Faculty Supervisor
- Project Coordinator
- Research Nurse
- Data Manager
- Pharmacist
- Safety Monitor
- Research Personnel
- Regulatory Staff
- Study Coordinator
- Student Assistant
- Lead Study Coordinator

3. \* Is the team member involved in the consent process?

- Yes  No [Clear](#)

4. \* Does the team member have a financial interest related to this research? ?

- Yes  No [Clear](#)

\* Required

OK

OK and Add Another

Cancel

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.

### Study Scope ?

1. \* Are there other research locations where the investigator will conduct or oversee the research? ?

- Yes  No [Clear](#)

2. \* Does the study specify the use of an approved drug or biologic, use an unapproved drug or biologic, or use a food or dietary supplement to diagnose, cure, treat, or mitigate a disease or condition? ?

- Yes  No [Clear](#)

3. \* Does the study evaluate the safety or effectiveness of a device or use a humanitarian use device (HUD)?

- Yes  No [Clear](#)



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](#).

## Research Locations

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

Location	Contact	Phone	Email
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	<input type="text"/>
Address line 2	<input type="text"/>
Address line 3	<input type="text"/>
City	<input type="text"/>
State or province	<input type="text" value="-- Select One --"/>
Postal code	<input type="text"/>
Country	<input type="text" value="-- Select One --"/>

c. Contact name:

d. Contact phone:


e. Contact e-mail:

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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:


		
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:

		
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) 

			
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:


		
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:


		
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) 


			
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.

## Local Site Documents

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


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

**2. Recruitment materials:** (add 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 site-related documents not attached on previous forms

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.

## 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.

<a href="#">« Back</a>	<a href="#">Save</a>	<a href="#">Exit</a>	<a href="#">Hide/Show Errors</a>	<a href="#">Print</a>	<a href="#">Jump To ▾</a>	<a href="#">Finish</a>
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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.

**Pre-Submission**

Entered IRB:  
Last updated: 6/14/2017 11:04 AM

**Status Change Alert**

**DRAFT SUBMISSION STAGE. Click "Submit" or "Notify PI" to send to IRB for review.**

**Next Steps**

- Edit Study
- Printer Version
- View Differences
- Submit
- Discard
- Assign Primary Contact
- Manage Ancillary Reviews
- Manage Guest List
- Copy Submission
- Add Comment
- NotifyPI

**STUDY00141108**

## Study Test 1

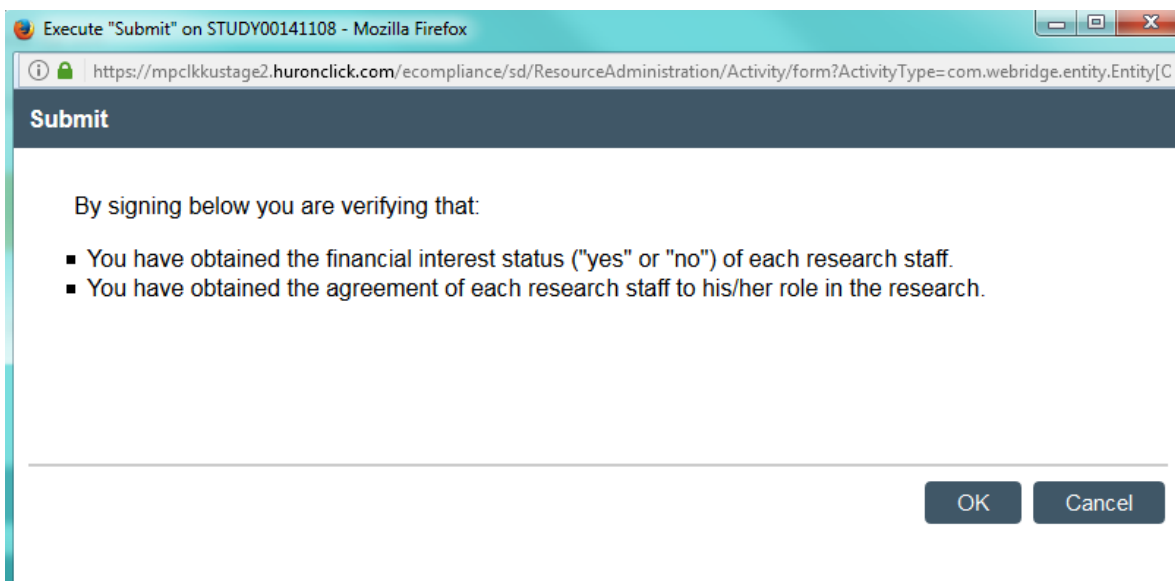
**Principal investigator:** HSCL test Test      **IRB office:** KU Lawrence  
**Submission type:** Initial Study  
**Primary contact:** HSCL test Test  
**IRB coordinator:**

**History** | Funding | Project Contacts | Documents | **Reviews** | Snapshots

**Filter** Activity | Enter text to search for | Go | + Add Filter | x Clear All

Activity	Author	Activity Date
Study Created	Test, HSCL test	6/14/2017 10:54 AM

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.



Please confirm your login credentials:

Username:

Password:

Submit

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.

Pre-Review

Entered IRB: 6/14/2017 11:10 AM  
Last updated: 6/14/2017 11:10 AM

Status Change Alert

Success! Your submission has been sent to the IRB.

Next Steps

View Study

Printer Version

View Differences

Withdraw

Discard

Assign Primary Contact

Manage Guest List

Copy Submission

Add Comment

(IRB - STUDY - in review)

STUDY00141108

# Study Test 1

Principal investigator: HSCL test Test  
Submission type: Initial Study  
Primary contact: HSCL test Test  
IRB coordinator:

IRB office: KU Lawrence



History	Funding	Project Contacts	Documents	Reviews	Snapshots
Filter <b>Activity</b> <input type="text" value="Enter text to search for"/> <input type="button" value="Go"/> <input type="button" value="+ Add Filter"/> <input type="button" value="x Clear All"/>					
Activity	Author	Activity Date			
Submitted	Test, HSCL test	6/14/2017 11:10 AM			
Study Created	Test, HSCL test	6/14/2017 10:54 AM			

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](#)