

## Creating an External Study in eCompliance

**\*\*NOTE:** An external study may only be used when an IRB Authorization Agreement (reliance agreement) is in place with another institution with a valid Federal Wide Assurance (FWA) number and IRB Registration number. Please contact [irb@ku.edu](mailto:irb@ku.edu) with any questions, or additional information on collaboration with other institutions.

1. To create a study, go to [ecompliance.ku.edu](http://ecompliance.ku.edu) and log in using your KU ID and password.
2. Click the "Create New Study" button in order to get started.

*NOTE: The default screen when you log in is the eCompliance inbox. This will only show you any projects that require action from the research team. To see all of your current studies, you can click "IRB" in the red banner.*

**My Current IRB Actions**

Create New Study

Report New Information

**My Current COI Activities**

Create "Update Certification"

**Shortcuts**

COI Help

IRB Help

**Web Page Links**

Custom Search Management

**My Inbox**

Combined IRB COI

Filter ID Enter text to search for Go + Add Filter x Clear All

ID	Name	SmartForm	Execute Activity	Date Created	State	Coordinator
STUDY00141144	Ancillary Review	[Edit]	▶	7/14/2017 9:42 AM	Pre-Submission	
STUDY00141143	Faculty Approval	[Edit]	▶	7/14/2017 9:34 AM	Pre-Review	
STUDY00141107	testing number 9	[Edit]	▶	6/14/2017 10:07 AM	Committee Review	Caitlin Carter

3 items page 1 of 1 10 / page

eCompliance : Conflict of Interest and Human Subjects Research  
KU Lawrence and Edwards campuses  
KU Medical Center, Kansas City KU School of Medicine, Wichita  
Contact Information for each Campus

3. On the Basic Information page, fill in information about the study. To create an external study, select **“Yes”** for question 7, “Will an external IRB act as the IRB of record for this study?”

## Basic Information

1. \* Title of study:

2. \* Short title:

3. \* Brief description: ?

4. \* Principal investigator:

HSCL test Test

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

Yes  No [Clear](#)

6. \* Which IRB should oversee this study?

- KU Lawrence  
 KUMC  
[Clear](#)

7. \* Will an external IRB act as the IRB of record for this study? (Once this selection is saved, it cannot be changed.)

Yes  No [Clear](#)

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](#)

4. On the next page, select the External IRB and upload the protocol/study documents, approval letter from the other institution, and the signed [IRB Authorization Agreement](#).

\*\*Note: If you do not see your collaborating institution in the list of External IRBs, please contact [irb@ku.edu](mailto:irb@ku.edu) to add it.

5. Click "Continue."

## External IRB

**1. \* External IRB:**

Duke University

**2. External study ID:**

**3. Approval letter from external IRB:**

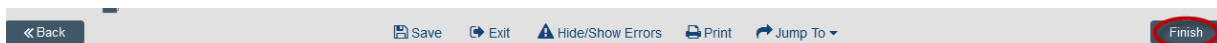
Duke University IRB Approval Letter(0.01)

**4. Initial approval date by external IRB:**

**5. Last day of approval period:**

**6. Specify the reason the study should be reviewed by an external IRB:**

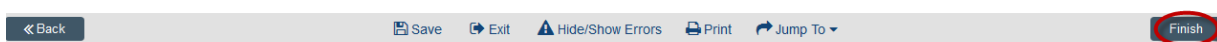
- Next, complete the rest of the application like a regular study. If you need more guidance on those steps refer to our [Creating a Multi-Site Study](#) guide. Once completed, click the “Finish” button on either the top or bottom of the screen.



### Final Page

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

- Click **Finish** to exit the form.
- Important!** To send the submission for review, the principal investigator must click **Submit** on the next page.



- This will take you to your study homepage. To submit your external study you will first need to go to the site page and submit the site. Click on the site listed by Local site to go to your site page.

**External IRB**

Initial approval:  
Approval end:  
Last updated: 1/12/2018 11:06 AM

**STUDY00141908: external**

Lead principal investigator: HSCL test Test  
Local site: [SITE00000270](#)

External IRB: Boston Children's Hospital  
External IRB approval letter:  
Regulatory authority:

Next Steps

- Edit Study
- Printer Version
- View Differences
- Report New Information

Correspond with sIRB  
Add Comment

History | Funding | Documents

Filter: Activity [v] Enter text to search for [Go] + Add Filter x Clear All

Activity	Author	Activity Date
Site Created	Test, HSCL test	1/12/2018 11:06 AM
Link: Site for external		
Study Created	Test, HSCL test	1/12/2018 11:06 AM

- On your site page, go to Edit Site to edit and submit your site.

**Pre-Submission** SITE00000270: Site for external

Last updated: 1/12/2018 11:06 AM

Principal investigator: IRB Site  
Submission type: IRB Site  
Primary contact:  
PI proxies:

IRB office: KU Lawrence  
IRB coordinator:  
Study: STUDY00141908  
External study ID:

**Next Steps**

- Edit Site
- Printer Version
- View Differences
- Assign Primary Contact
- Manage Guest List
- Add Comment
- Discard
- NotifyPI

**Workflow Diagram:**

```
graph LR; Pre-Submission --> Pre-Review; Pre-Review --> Pending_sIRB_Review; Pending_sIRB_Review --> Post-Review; Post-Review --> Review_Complete; Clarification_Requested --> Pre-Review; Modifications_Required --> Post-Review;
```

**Activity History:**

Activity	Author	Activity Date
Site Created	Test, HSCL test	1/12/2018 11:06 AM

9. Next, re-enter in your brief description, principal investigator, and answer question 5.

### Basic Information

1. \* Title of site:

Site for External

2. \* Short title:

Site for external

3. \* Brief description: ?

|

4. \* Principal investigator:

...

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

Yes  No [Clear](#)

6. \* Which IRB should oversee this study?

KU Lawrence  
 KUMC  
[Clear](#)

10. Click continue and go through the Site as normal. There will be a page for local site documents where you can upload documents specific to your site.

## 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

11. Next, submit your site for HRPP review. Click the “Submit” button on the left side of the screen. The system will ask you to enter your KU ID and password.

**Pre-Submission**

Last updated: 1/12/2018 11:09 AM

**Next Steps**

- Edit Site
- Printer Version
- View Differences
- Submit** →
- Assign Primary Contact
- Manage Ancillary Reviews
- Manage Guest List
- Correspond with sIRB
- Add Comment
- Discard
- NotifyPI

### SITE00000270: Site for external

Principal investigator: HSCL test Test  
 Submission type: IRB Site  
 Primary contact: HSCL test Test  
 PI proxies:

IRB office: KU Lawrence  
 IRB coordinator:  
 Study: STUDY00141908 ?  
 External study ID:

History: Funding | Contacts | Documents | Reviews | Snapshots

Filter: Activity ?

Activity	Author	Activity Date
Site Created	Test, HSCL test	1/12/2018 11:06 AM

12. Once the study is submitted, the flowchart will change from “Pre-Submission” to “Pre-Review” and the History Activity will show that the study has been “Submitted”. There will also be a green banner at the top of your screen for a few seconds to show submission.

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

Printer version

**Principal investigator:** Anita Anderson  
**Submission type:** Continuing Review  
**Primary contact:** Anita Anderson  
**IRB coordinator:**

**IRB office:** KU Lawrence

← Withdraw

⊗ Discard

💬 Add Comment

(IRB - Mod/CR - In-Review)



History

Project Contacts

Documents

Related RNIs

Snapshots

Filter ?

Activity

Enter text to search for

Go

+ Add Filter

✕ Clear All

Activity

Author

▼ Activity Date

Submitted

Anderson, Anita

7/26/2017 2:31 PM

Human Research Protection Program

[irb@ku.edu](mailto:irb@ku.edu)

785-864-7429 ext. 1

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

#### Quickstart

- ✓ [Creating a Single-Site Study](#)
- ✓ [Creating a Multi-Site Study](#)
- ✓ [Continuing Review](#)
- ✓ [Accessing a Study](#)
- ✓ [Changing Principle Investigator](#)
- ✓ [Adding Funding](#)
- ✓ [Modification](#)
- ✓ [Study Team Modification](#)
- ✓ [Responding to Clarifications](#)
- ✓ [Closing a Study](#)

#### Guides

- ✓ [Student Ancillary Review Guide](#)
- ✓ [Faculty Supervisor Ancillary Review Guide](#)