

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 with any questions, or additional information on collaboration with other institutions.

1. To create a study, go to 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:

Anita Anderson

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
 - KUSM-W
- [Clear](#)

7. * Will an external IRB act as the IRB of record for this study?

Yes No [Clear](#)

- 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 to add it.

- Click "Continue."

External IRB

1. * External IRB: ?

Duke University ...

2. IRB authorization agreement: (if no existing agreement covers this study) ?

+ Add

Name

There are no items to display

3. Approval letter from external IRB:

hsc1-app.pdf(0.01)

Upload Revision

4. Initial approval date by external IRB: ?

7/13/2017

5. Last day of approval period: ?

7/14/2017

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

External IRB

<< Back

Save

Exit

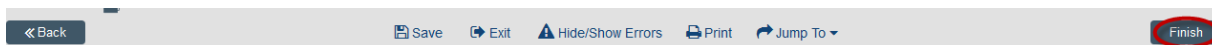
Hide/Show Errors

Print

Jump To

Continue >>

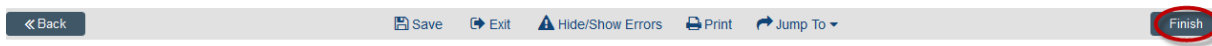
- Next, complete the rest of the application like a regular study. If you need more guidance on those steps refer to our [Creating a Study](#) guide. Once completed, click the “Finish” button on either the top or bottom of the screen.



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.



- In order to submit your study for review by HRPP staff, 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

Entered local IRB:
Last updated: 7/14/2017 11:29 AM

Next Steps

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

Status Change Alert

DRAFT SUBMISSION STAGE. Click “Submit” or “Notify PI” to send to IRB for review.

STUDY00141146: Test

Principal investigator: Anita Anderson
Submission type: Initial Study
Primary contact: Anita Anderson
IRB coordinator:

IRB Office: KU Lawrence
External IRB: Duke University
External IRB Approval Letter: hsc1-app.pdf(0.01)

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graph LR; A[Pre-Submission] --> B[Pre-Review]; B --> C[Post-Review]; C --> D[Review Complete]; B --> E[Clarification Requested]; E --> B;
```

History	Funding	Project Contacts	Documents	Follow-on Submissions	Reviews	...
Filter <input type="text" value="Activity"/> <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						
Study Created Anderson, Anita 7/14/2017 11:27 AM						

8. 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.

The screenshot displays the IRB system interface. At the top left, there are navigation options: "Printer Version", "Withdraw", "Discard", and "Add Comment". On the top right, the "IRB office: KU Lawrence" is indicated. The central part of the screen features a flowchart with the following stages: "Pre-Submission", "Pre-Review" (highlighted in orange), "IRB Review", "Post-Review", and "Review Complete". Below these stages are boxes for "Clarification Requested" and "Modifications Required", with arrows indicating feedback loops. A red arrow points from the "IRB coordinator:" label to the "Pre-Review" stage. Below the flowchart is a "History" section with tabs for "Project Contacts", "Documents", "Related RNIs", and "Snapshots". A filter is set to "Activity". A search bar contains the text "Enter text to search for" and a "Go" button. Below the filter is a table with the following data:

Activity	Author	Activity Date
Submitted	Anderson, Anita	7/26/2017 2:31 PM

A red arrow points to the "Submitted" activity in the table.

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

Quickstart

- ✓ [Creating a 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](#)