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.`
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:*
   
   External Study

2. *Short title:*
   
   Test

3. *Brief description:*
   
   External Study Test

4. *Principal investigator:*
   
   HSCL test Test

5. *Does the investigator have a financial interest related to this research?*
   
   ![Yes](Yes) ![No](No)

6. *Which IRB should oversee this study?*
   
   ![KU Lawrence](KU Lawrence) ![KUMC](KUMC)

7. *Will an external IRB act as the IRB of record for this study? (Once this selection is saved, it cannot be changed.)*
   
   ![Yes](Yes) ![No](No)

8. *What kind of study is this? (Once this selection is saved, it cannot be changed.)*
   
   ![Single-site study](Single-site study) ![Multi-site study](Multi-site study)
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 to add it.

5. Click “Continue.”

**External IRB**

1. * External IRB:
   Duke University

2. External study ID:
   123456

3. Approval letter from external IRB:
   Duke University IRB Approval Letter(3.01) [Uploaded Revision]

4. Initial approval date by external IRB:
   1/1/2018

5. Last day of approval period:
   12/31/2019

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

Human Research Protection Program
   irb@ku.edu
   785-864-7429 ext. 1
6. 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.

7. 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.

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

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.
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.

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

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

Review Complete
Post-Review
Modifications Required
Clarification Requested
Clarification Requested
Pre-Review
IRB Review

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

Filter Activity
Enter text to search for Go + Add Filter × Clear All
Activity Author Activity Date

Human Research Protection Program
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