

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 hscl@ku.edu with any questions, or additional information on collaboration with other institutions.

STEP 1: To create a study, go to ecompliance.ku.edu and log in using your KU ID and password.

STEP 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 show you any projects that require action from the research team.

The screenshot displays the eCompliance web application interface. At the top, the University of Kansas logo is visible on the left, and the user's name 'Anita Anderson | My Inbox | Logoff' is on the right. Below the logo, there are navigation links for 'Home', 'IRB', and 'COI'. The main content area is titled 'Page for Anita Anderson'. On the left side, there is a 'Current IRB Actions' menu with a yellow circle around it, containing 'Create New Study' and 'Report New Information'. Below this is a 'Shortcuts' section with links for 'COI Help' and 'IRB Help'. The main area shows a table of IRB actions with columns: ID, Name, SmartForm, Execute Activity, Date Created, Date Modified, State, Owner, and PI Action Required. The table contains several rows of study entries. At the bottom of the page, there is a footer with the text 'eCompliance : Conflict of Interest and Human Subjects Research KU Lawrence and Edwards campuses'.


ID	Name	SmartForm	Execute Activity	Date Created	Date Modified	State	Owner	PI Action Required
STUDY00000022	Demo of a study that has provisos	[Edit]	Execute	6/27/2013 3:47 PM	7/5/2013 4:01 PM	Modifications Required		no
STUDY00000028	new study to demonstrate clarifications in Pre-Review	[Edit]	Execute	6/28/2013 1:07 PM	7/5/2013 3:54 PM	Clarification Requested (Pre-Review)		no
STUDY00000041	Study created for Dr. Simms by the Regulatory Office	[Edit]	Execute	7/5/2013 3:01 PM	7/5/2013 3:12 PM	Pre-Submission		no
STUDY00000013	Demo of Notify PI button	[Edit]	Execute	6/25/2013 2:55 PM	7/2/2013 5:05 PM	Clarification Requested (Pre-Review)	George Garretson	no
STUDY00000026	Visibility to the ancillary reviewers	[Edit]	Execute	6/28/2013 7:54 AM	6/28/2013 7:54 AM	Pre-Submission		no
RNI00000003	Report of PRMC action	[Edit]	Execute	6/27/2013 4:09 PM	6/27/2013 4:09 PM	Pre-Submission		no
RNI00000001	SERious adverse event	[Edit]	Execute	6/24/2013 2:36 PM	6/27/2013 2:34 PM	Clarification Requested (RNI Review)	George Garretson	no
STUDY00000017	ancillary	[Edit]	Execute	6/27/2013 10:38 AM	6/27/2013 10:57 AM	Pre-Submission		no

STEP 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](#)




STEP 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 hscl@ku.edu to add it.

STEP 5: Click “Finish.”

External IRB

1. * External IRB: 

Duke University

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

Name
There are no items to display

3. Approval letter from external IRB:

Approval Letter.docx(0.01)

4. Initial approval date by external IRB:

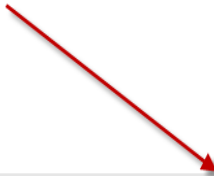
09/9/2015

5. Last date of approval period:

09/16/2015

6. Supporting documents:

Name
 Protocol



STEP 5: In order to submit your study for review by HSCL staff, click the “Submit” button on the left side of the screen.

My Current Actions

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

History	Funding	Project Contacts	Documents	Reviews	Snapshots	
Filter by	Activity			Go	Clear	Advanced
Activity				Author		
	Study Created			Anderson, Anita		

Looking for something else? There is more information available on the HSCL website:

Quickstart

- ✓ Creating a Study
- ✓ Continuing Review
- ✓ Responding to Clarifications
- ✓ Closing a Study

Guides

- ✓ [Student/Faculty Supervisor Submission Guide](#)
- ✓ [Study Submission Guide](#)

FAQs

- ✓ [eCompliance FAQs](#)