

Creating a Study in eCompliance

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.

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

NOTE: eCompliance is a submission system that is made of form pages with specific sets of questions grouped together on the pages, like “Basic Information”, “Funding Sources”, Study Staff”, etc. Different pages will ask you to answer certain questions or to upload specific documents.

STEP 3: Work through the pages by answering questions and uploading documents. The Basic Information page, question 8, is where you can attach the **application**. Please note that there is a different location to upload other documents—including consent forms and procedures—do not upload those documents in the protocol field.

NOTE: If you do not have the current version of the application, which was revised on June 17, 2013, and you do not know where to find it, click on the HRP-503-ProtocolLinks link, or visit our website.

Checklist of Documents in eCompliance	
eCompliance Page	Documents to Prepare and Upload
Basic Information	*Initial Submission Application
Funding Sources	Grant applications or award letter (if applicable)
Study Team Members	For non-KU affiliates, submit IRB Access form to HSCL@ku.edu prior to final submission.
Study Scope	N/A
External Sites (if checked in Study Scope)	IRB Reliance letter (if available). Letter of support (if applicable)
Consent Form and Recruitment Materials	Consent Documents (Signed consent, information statement, etc.) and recruitment materials (flyers, emails, letters, etc.)
Supporting Documents	If Applicable: <ul style="list-style-type: none"> • Surveys, instruments • Data collection sheet • Subject instructions, diaries, etc. • Sponsor correspondence • HIPAA waiver request • Etc.
	*Required on all new studies

*NOTE: Consent forms **must** be uploaded in the “Consent forms” section on the “Consent Forms and Recruitment Materials” page.*

STEP 4: Click “Finish.” Pay attention to point 2 on the final page—you will need to click SUBMIT on the next page after you click “finish.”

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.

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Save | Exit | Hide/Show Errors | Print... | Jump To:

Finish



STEP 5: In order to submit your study for review by HSCL staff, click the “Submit” button on the left side of the screen. If you are not the PI on the project, then the PI will need to log in and click the “Submit” button.

NOTE: Students who are submitting a study will need to create an ancillary review for their faculty advisor before submitting their project for review. This can be done by clicking “Manage ancillary reviews,” Clicking “Add” and finding the faculty member’s name. Please make sure you note that a response IS required. See the Student guide for detailed instructions.

Home IRB COI

IRB > IRB Submissions > Study Test 1

Pre-Submission **STUDY00000043: Study Test 1** IRB office: KU Lawrence

Entered IRB: Principal investigator: Anita Anderson
 Initial approval: Submission type: Initial Study
 Effective: Primary contact: Anita Anderson
 Approval end: IRB coordinator:
 Modified: 7/8/2013 10:37 AM

Pre-Submission → IRB Pre-Review → IRB Review → Post Review → Review Complete
 (Clarifications Requested) (Clarifications Requested) (Modifications Required)

My Current Actions

- Edit Study
- Printer Version
- View Differences
- Submit**
- Discard
- Assign Primary Contact
- Manage Guest List
- Copy Submission
- Ac...

History Project Contacts Documents Reviews Snapshots

Filter by Activity Go Clear Advanced

Activity	Author	Activity Date
Study Created	Anderson, Anita	7/8/2013 10:32 AM CDT

*NOTE: Once you have submitted your study, you can check on the progress of your submission by logging in and viewing the **status bar**.*

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

Quickstart

- ✓ Creating a Study
- ✓ Modification and Continuing Review
- ✓ Continuing Review Determination Guide
- ✓ Closing a Study

Guides

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

FAQs

- ✓ [eCompliance FAQs](#)