

# INVESTIGATOR GUIDANCE

## Submitting a New Study in eIRB

The eCompliance software allows you to prepare your study documents in advance and then upload them for electronic review. Please refer to the last page of this document for a list of documents to prepare.

Start your electronic submission by logging in to the Home Page at: <https://ecompliance.ku.edu>. You will log in with your regular email user name and password.

Logging in takes you to your personalized **Home Page**. On the left, you will notice a button to **Create New Study**.

**My Current IRB Actions**

Create New Study

Report New Information

**My Current COI Activities**

Create "Update Certification"

**Shortcuts**

COI Help

IRB Help

**Reports**

**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
STUDY00141783	Study 1	[Edit]		12/14/2017 10:47 AM	Pre-Submission	

1 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

Once you select **Create New Study** you will be directed to the first of **9 required tabs**. As you complete the questions, you may also be prompted to answer questions on **3 additional tabs** relating to external research locations, drugs, and devices, if applicable to your study.

### **BASIC INFORMATION**

*Notes:*

- The **Short Title** is how the study is referenced throughout the system.
- For item #6, select the KUMC IRB. Consult the IRB office for further instructions if the study will be conducted on the Lawrence campus.  
(corresponding screenshot on next page)

## Basic Information

1. \* Title of study:

Put the full title of the study here

2. \* Short title:

This short title is the name that will show when you access the study

3. \* Brief description: ?

Please type 2 - 3 sentences about the study to help the IRB staff quickly triage your review.

4. \* Principal investigator:

Nancy Nelson ...

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.)

Multi-site study (More than one site will conduct the entire study)  
 Single-site study  
[Clear](#)

9. \* Attach the protocol:

[+ Add](#)

Document	Category	Date Modified	Document History
There are no items to display			

- For item #8, please select either Multi-site or Single-site study.
  - If you select **Multi-site study**, an additional question will appear asking if your IRB will act as the single IRB of record.
  - Please note that for questions #7, #8, and #9 (if Multi-site was selected) the selection **cannot be changed** once it has been saved. If you have questions regarding which selection to make, please consult the IRB office.
- 9. \* Will your IRB act as the single IRB of record for other participating sites? (Once this selection is saved, it cannot be changed.)
  - Yes  No [Clear](#)
- To attach the protocol, choose **Add** to upload your protocol.

## FUNDING SOURCES

Notes:

- Choose **Add** to go to a drop-down list of sponsors.
- The drop-down list is auto-populated with all the current sponsors at KU/KUMC.
  - Contact the IRB office if you do not find your funding source; we will have it added.
- You may choose multiple funding sources.
- If you have grant funding, the IRB office must review the entire grant. You will be prompted to upload it on this page.
- You may hit **Continue** and skip this tab if your study is unfunded.



### Funding Sources

1. Identify each organization supplying funding for the study:

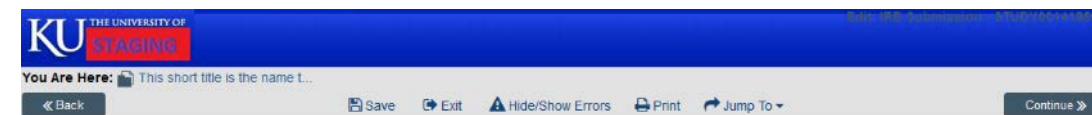
Funding Source	Sponsor's Funding ID	Grants Office ID	Attachments
There are no items to display			



## STUDY TEAM MEMBERS

Notes:

- Select your study team from the drop down list. All KUMC employees, residents and students have been populated to this list. Additionally, many KUH and UKP personnel have been added. KU Lawrence faculty also are listed.
- Contact the IRB office if you do not find an individual's name or if you are working with an outside collaborator; we will instruct you on how to have them added.



### Study Team Members

1. Identify each additional person involved in the design, conduct, or reporting of the research:

	Name	Roles	Financial Interest	Involved in Consent	E-mail	Phone
<input type="button" value="Update"/>	Nathan Ness	Co-investigator	no	yes	humansubjects@kumc.edu	<input type="button" value="🗕"/>
<input type="button" value="Update"/>	Patricia Peterson	Co-investigator	yes	yes	humansubjects@kumc.edu	<input type="button" value="🗕"/>
<input type="button" value="Update"/>	Rachel Reyes	Regulatory Staff	no	no	humansubjects@kumc.edu	<input type="button" value="🗕"/>
<input type="button" value="Update"/>	Stefano Smith	Data Manager	no	no	humansubjects@kumc.edu	<input type="button" value="🗕"/>



## STUDY SCOPE

Notes:

- This page has branching logic on all three questions. If your study involves external research locations, drugs or devices, you will complete this page and then provide details in subsequent pages.

The screenshot shows the top of the KU STAGING web application. It features a blue header with the KU logo and 'STAGING' text. Below the header is a navigation bar with buttons for 'Back', 'Save', 'Exit', 'Hide/Show Errors', 'Print', 'Jump To', and 'Continue'.

### Study Scope

1. \* Are there other research locations where the investigator will conduct or oversee the research?   
 Yes  No [Clear](#)
2. \* Does the study specify the use of an approved drug or biologic, use an unapproved drug or biologic, or use a food or dietary supplement to diagnose, cure, treat, or mitigate a disease or condition?   
 Yes  No [Clear](#)
3. \* Does the study evaluate the safety or effectiveness of a device or use a humanitarian use device (HUD)?  
 Yes  No [Clear](#)

The screenshot shows the navigation bar of the KU STAGING web application, including buttons for 'Back', 'Save', 'Exit', 'Hide/Show Errors', 'Print', 'Jump To', and 'Continue'.

### Research Locations (if applicable)

- Add each external research location and their contact.
- Feel free to contact our office with questions about this section.

The screenshot shows the top of the KU STAGING web application, including the header with the KU logo and 'STAGING' text, and the navigation bar with buttons for 'Back', 'Save', 'Exit', 'Hide/Show Errors', 'Print', 'Jump To', and 'Continue'.

### Research Locations

1. \* Identify other research locations where the investigator will conduct or oversee the research:

The screenshot shows a table for adding research locations. It has a '+ Add' button and a table with columns for Location, Contact, Phone, and Email. Below the table, it says 'There are no items to display'.

Location	Contact	Phone	Email
There are no items to display			

The screenshot shows the navigation bar of the KU STAGING web application, including buttons for 'Back', 'Save', 'Exit', 'Hide/Show Errors', 'Print', 'Jump To', and 'Continue'.

### Drugs (if applicable)

- Add each drug being used in the study.
- If you are using FDA-approved drugs, look on the first line of the secondary screen, which is auto-populated with drugs in the KU Hospital formulary.
- Investigational drugs are typed in by hand.
- Upload the investigator's brochure if applicable.
- Indicate the IND and IND holder if applicable.  
(topic continued on next page)

## Drugs

1. \* List all drugs, biologics, foods, and dietary supplements to be used in the study:

+ Add			
	Generic Name	Brand Name	Attachment Name
	acetaminophen	TYLENOL	
	Investigational Drug Name		Investigator's Brochure

2. \* Will the study be conducted under any IND numbers?

Yes  No [Clear](#)

3. \* Identify each IND:

+ Add		
IND Number	IND Holder	Other Holder
123456	Sponsor	

4. Attach files: (such as IND or other information that was not attached for a specific drug)

+ Add			
Document	Category	Date Modified	Document History
There are no items to display			

## Devices (if applicable)

- Add each device being used in the study.
- Devices are typed in by hand on the second line of the secondary screen.
- Upload the device manual, if applicable.
- Indicate the IDE and IDE holder, if applicable.

## Devices

1. \* Select each device the study will use as an HUD or evaluate for safety or effectiveness:

+ Add			
	Device	Humanitarian Use Device	Attachment Name
	Cardiac stent	no	Instructions for Use

2. \* Device exemptions applicable to this study:

- IDE number  
 HDE number  
 Claim of abbreviated IDE (nonsignificant risk device)  
 Exempt from IDE requirements  
[Clear](#)

3. Attach files: (such as IDE, HDE, or other information that was not attached for a specific device)

+ Add			
Document	Category	Date Modified	Document History
There are no items to display			

# **LOCAL SITE DOCUMENTS**

## **Consent forms:**

Notes:

- If your study involves written consent materials, choose “Add” to upload them in this section.
- Multiple consent documents can be added.
- Please be mindful of how you name the attachments. The document name you enter will be the exact name that prints out on your approval letter.
- The consent documents should be in Word, with no footer. Allow a 1” bottom margin so that the electronic system can add a footer to the approved document.
- Note the electronic system automatically adds a versioning code (0.01). Versioning will be updated by the system if you modify the document at a later date.

## **Recruitment materials:**

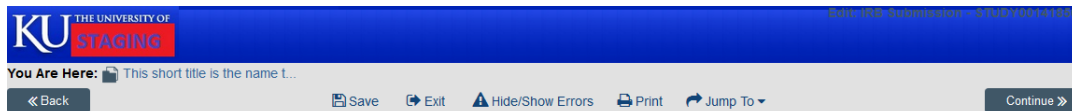
Notes:

- If recruitment materials are available, you may add them with the initial submission.

## **Other attachments:**

Notes:

- Use this section to upload all other documents required for IRB review.
- Every initial submission will be accompanied by an appropriate Project Description, whether for Full Committee, Expedited, Exempt or Retrospective projects. The Project Description helps the IRB determine whether the proposal meets federal criteria for approval. Project Descriptions are posted on the IRB website at: <http://www.kumc.edu/compliance/human-research-protection-program/institutional-review-board/forms.html>.
- In addition to the Project Description, multiple documents can be added.
- Please classify your documents by applicable category.



### 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) ?

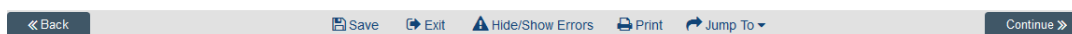
Document	Category	Date Modified	Document History
There are no items to display			

#### 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



# INTERNAL REPORTING

## Notes:

- This page has been customized for KUMC. It provides information for NCI and CTSA reporting as well as local reporting requirements.

**KU** THE UNIVERSITY OF **STAGING** Final IRB Submission - 3/10/2014/101

You Are Here: This short title is the name t...

« Back Save Exit Hide/Show Errors Print Jump To Continue »

## Internal Reporting

### 1. \* Categorize your study as one of the following:

Category	Description
<input type="radio"/> Interventional	Study in which individuals are assigned by an investigator based on a protocol to receive specific interventions. The participants may receive diagnostic, therapeutic, behavioral or other types of interventions. The assignment of the intervention may or may not be random. The participants are followed and biomedical and/or health outcomes are assessed.
<input type="radio"/> Observational	Study in which the studies focus on participants and healthy populations that involve no intervention or alteration in the status of the participants. Biomedical and/or health outcome(s) are assessed in pre-defined groups of participants. The participants in the study may receive diagnostic, therapeutic, or other interventions but the investigator of the observational study is not responsible for assigning specific interventions to the participants of the study.
<input type="radio"/> Ancillary	Study that is stimulated by, but is not a required part of, a main research study, and that utilizes participant or other resources of the project to generate information relevant to it. Ancillary studies must be linked to an active clinical research study and should include only participants accrued to that clinical research study. Only studies that can be linked to individual participant or participant data should be reported.
<input type="radio"/> Correlative	Laboratory based study using specimens to assess disease risk, clinical outcomes, response to therapies, etc. Only studies that can be linked to individual participant or participant data should be reported.
<input type="radio"/> None	Excluded from the above definitions are in vitro studies that utilize human tissues that cannot be linked to a living individual, tissue banking, and studies that do not require participant consent (e.g., retrospective chart reviews).

[Clear](#)

### 2. \* Is the study cancer or cancer-related?

Yes  No [Clear](#)

### 3. \* Is the study investigator-initiated?

Yes  No [Clear](#)

### 4. \* Will your study take place at Wichita?

Yes  No [Clear](#)

### 5. \* Does the study team include persons who are external to KUMC?

Yes  No [Clear](#)

« Back Save Exit Hide/Show Errors Print Jump To Continue »

# FINAL PAGE

Click Finish to save and exit the form.

**KU** THE UNIVERSITY OF **STAGING** Final IRB Submission - 3/10/2014/101

You Are Here: This short title is the name t...

« Back Save Exit Hide/Show Errors Print Jump To 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, click **Submit** on the next page.

« Back Save Exit Hide/Show Errors Print Jump To Finish »

# MAIN STUDY PAGE

Now your study is created. Notice that the study is still in **Pre-Submission** status and has not been sent to the IRB. Both the yellow flow chart bubble and the yellow status bar indicate **Pre-Submission**. An orange **Draft Submission Stage** banner is also visible at the top of the page.

As long as the study is in Pre-Submission, the study can be edited by the PI or study team. The study stays in Pre-Submission until the PI hits the **Submit** button. Any member of the study team can create a study, but only the principal investigator has the **Submit** button. Other team members will see a button that says **Notify PI**.

The screenshot shows the 'STUDY00141856: Demo of a new study' page. At the top, a blue navigation bar includes 'My Inbox', 'Home', 'IRB', and 'COI'. Below this is a red banner with 'Submissions', 'Meetings', 'Library', 'Reports', and 'Help Center'. A yellow 'Pre-Submission' status bar is prominent. An orange banner reads 'DRAFT SUBMISSION STAGE. Click "Submit" or "Notify PI" to send to IRB for review.' The 'Next Steps' section contains buttons for 'Edit Study', 'Printer Version', and 'View Differences'. A flowchart illustrates the process: Pre-Submission (yellow) leads to Pre-Review, which can lead to IRB Review or Clarification Requested. IRB Review can lead to Post-Review or Clarification Requested. Post-Review can lead to Review Complete or Modifications Required. Clarification Requested can lead back to Pre-Review or IRB Review. Modifications Required can lead back to Post-Review. Below the flowchart is a 'History' table with tabs for Funding, Contacts, Documents, Reviews, and Snapshots. The 'Activity' tab is selected, showing a search bar and a table with one entry: 'Study Created' by 'Nelson, Nancy' on '12/27/2017 10:37 AM'. A left sidebar contains various management actions like 'Submit', 'Assign Primary Contact', 'Manage Ancillary Reviews', 'Manage Guest List', 'Add Comment', 'Copy Submission', 'Discard', and 'NotifyPI'.



## **SUBMIT THE STUDY**

Notice that once the study is submitted, the yellow flow chart bubble moves to the **Pre-Review** status. Note also that the submission has been locked and the **Edit Study** button has been replaced with **View Study**. A green banner will flash across the top of the screen as indicated below to confirm successful submission of the study. If desired, the PI can add a comment with the submission. The comment is viewable by anyone who has access to the study.

The screenshot shows the IRB system interface for a study titled "STUDY00141856: Demo of a new study". The user is Nancy Nelson. The status is "Pre-Review", and a green banner indicates "Success! Your submission has been sent to the IRB." The flowchart shows the process: Pre-Submission -> Pre-Review (highlighted) -> IRB Review -> Post-Review -> Review Complete. There are also "Clarification Requested" and "Modifications Required" paths. The activity log shows "Submitted" and "Study Created" actions.

**Pre-Review**

Entered IRB: 12/27/2017 11:23 AM  
Last updated: 12/27/2017 11:23 AM

**Status Change Alert**

Success! Your submission has been sent to the IRB.

**Next Steps**

- View Study
- Printer Version
- View Differences

Assign Primary Contact  
Manage Guest List  
Add Comment  
Copy Submission  
Withdraw  
Discard

**STUDY00141856: Demo of a new study**

Principal investigator: Nancy Nelson  
Submission type: Initial Study  
Primary contact: Nancy Nelson  
PI proxies:

IRB office: KUMC  
IRB coordinator:

Pre-Submission -> Pre-Review -> IRB Review -> Post-Review -> Review Complete

Clarification Requested (between Pre-Review and IRB Review)  
Clarification Requested (between IRB Review and Post-Review)  
Modifications Required (between Post-Review and Review Complete)

History | Funding | Contacts | Documents | Reviews | Snapshots

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

Activity	Author	Activity Date
Submitted	Nelson, Nancy	12/27/2017 11:23 AM
Study Created	Nelson, Nancy	12/27/2017 10:37 AM

## **PRE-REVIEW, COMMITTEE REVIEW, NON-COMMITTEE REVIEW OR POST REVIEW**

While the study remains viewable, it cannot be edited while its status displays one of these categories. The IRB staff or committee members are reviewing it and may request clarifications from you.

<b>Checklist of Documents for Human Subjects Committee Application in eCompliance</b>	
<b>eCompliance Screen</b>	<b>Documents to Prepare and Upload</b>
<b>Basic Information</b>	*Proposed study protocol
<b>Funding Sources</b>	Grant applications (if applicable)
<b>Study Team Members</b>	N/A
<b>Study Scope</b>	N/A
<b>External Sites (if checked in Study Scope)</b>	IRB Reliance letter (if available). Letter of support (if applicable)
<b>Drugs (if checked in Study Scope)</b>	For investigational drugs: Investigator's brochure, FDA letters (if applicable)
<b>Devices (if checked in Study Scope)</b>	Device Manual
<b>Consent Form and Recruitment Materials</b>	All proposed consent forms <u>in Word only with no footer</u> . All proposed recruitment materials
<b>Internal Reporting</b>	N/A
<b>Supporting Documents</b>	<p>*Project Description for Full Committee Review, Exempt, Expedited, or Retrospective Studies</p> <p>If Applicable:</p> <ul style="list-style-type: none"> <li>• Scientific merit review</li> <li>• Surveys, instruments</li> <li>• Data collection sheet</li> <li>• DSMB or DMC Charter</li> <li>• Subject instructions, diaries, etc.</li> <li>• Ancillary approval letter (e.g., RSC, Nursing Impact, PRMC)</li> <li>• Sponsor correspondence</li> <li>• HIPAA waiver request</li> </ul>
	<b>*Required on all new studies</b>