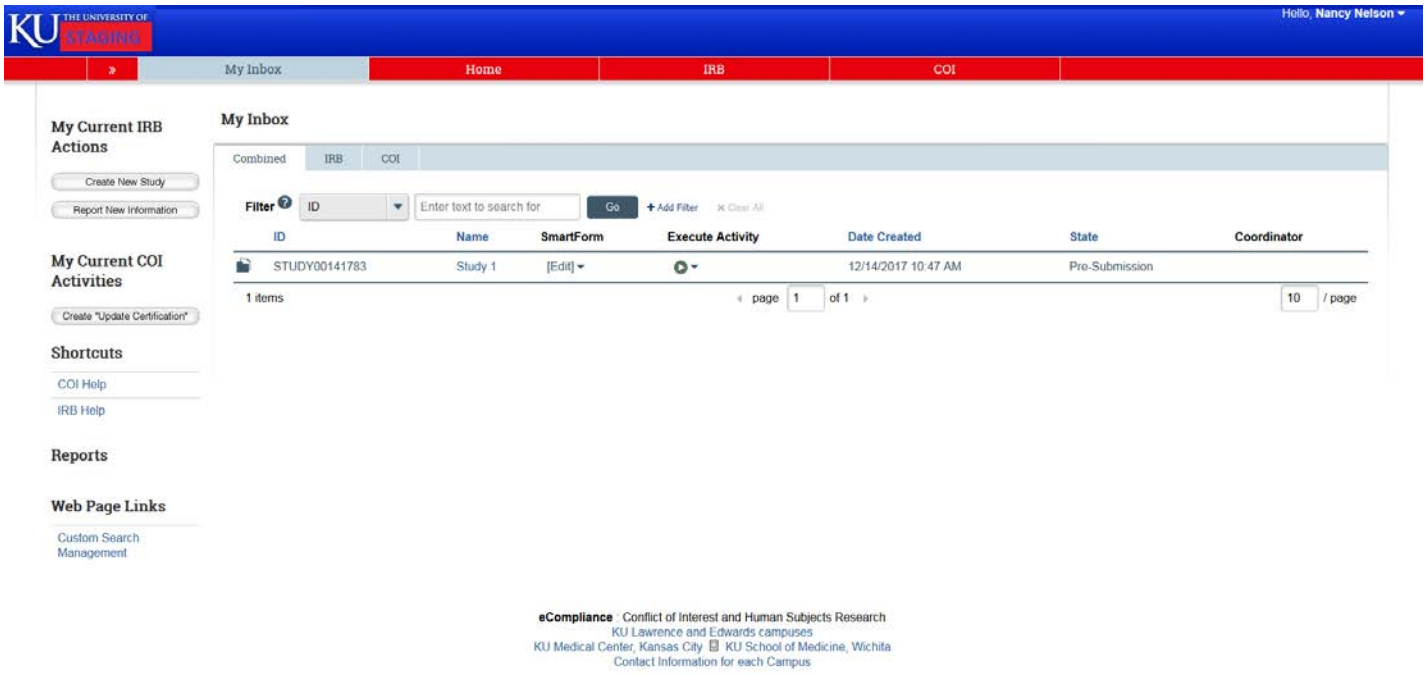
INVESTIGATOR GUIDANCE
Submitting a New Study in eIRB

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**.

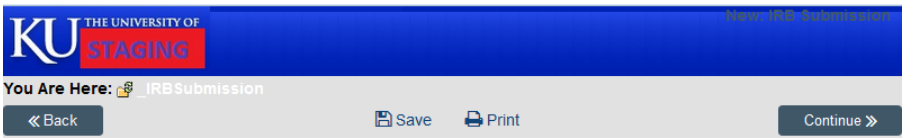


Once you select **Create New Study** you will be directed to the first of **9 required tabs.** As you complete the questions, you may also be prompted to answer questions on **3 additional tabs** relating to external research locations, drugs, and devices**,** if applicable to your study.

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

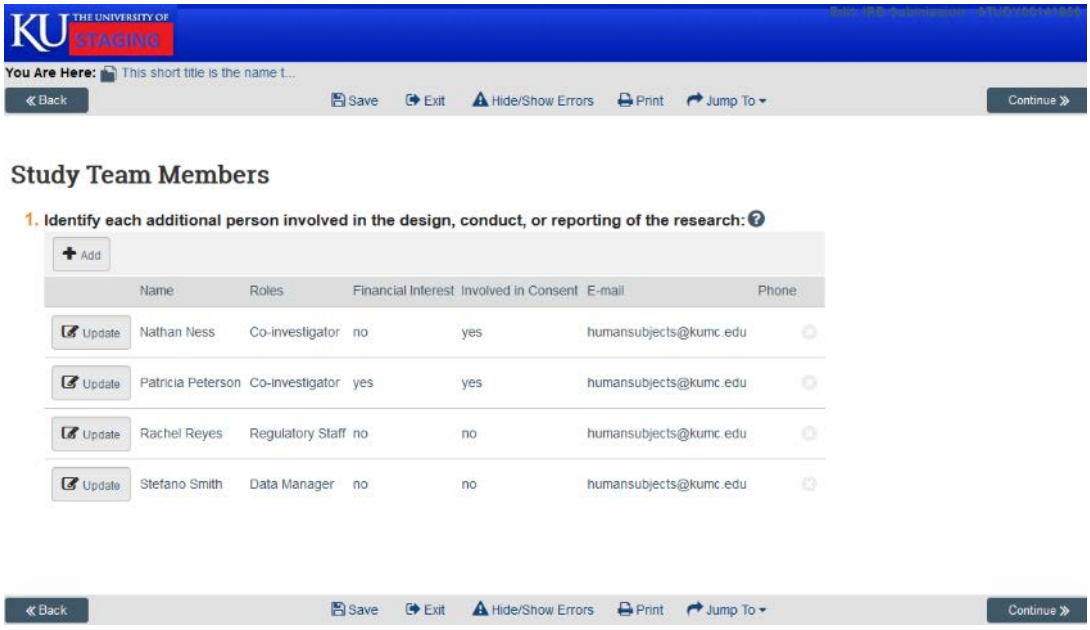
Notes:

- 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.

STUDY TEAM MEMBERS

Notes:

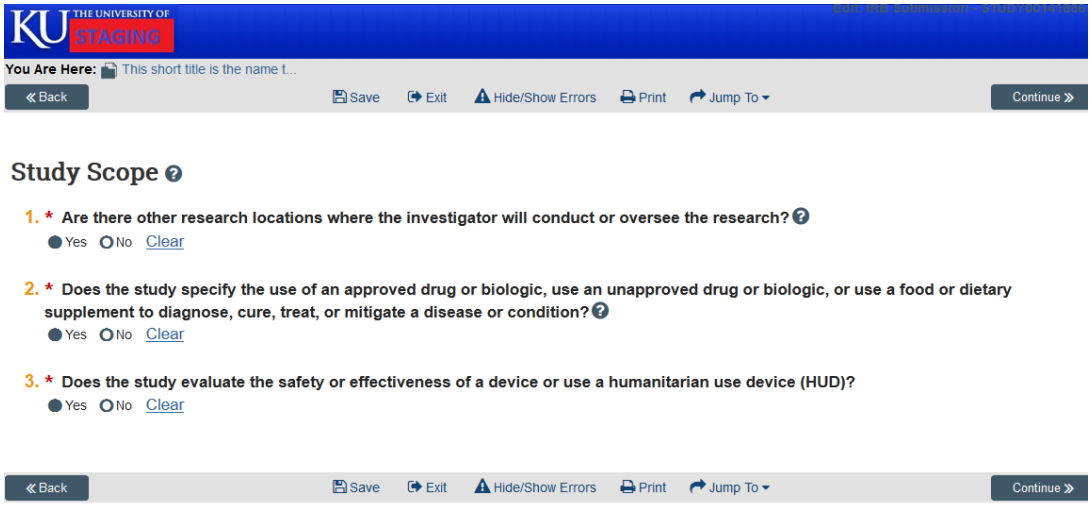
- Select your study team from the drop down list. All KUMC employees, residents and students have been populated to this list. Additionally, many KUH and UKP personnel have been added. KU Lawrence faculty also are listed.
- Contact the IRB office if you do not find an individual's name or if you are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



STUDY 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.



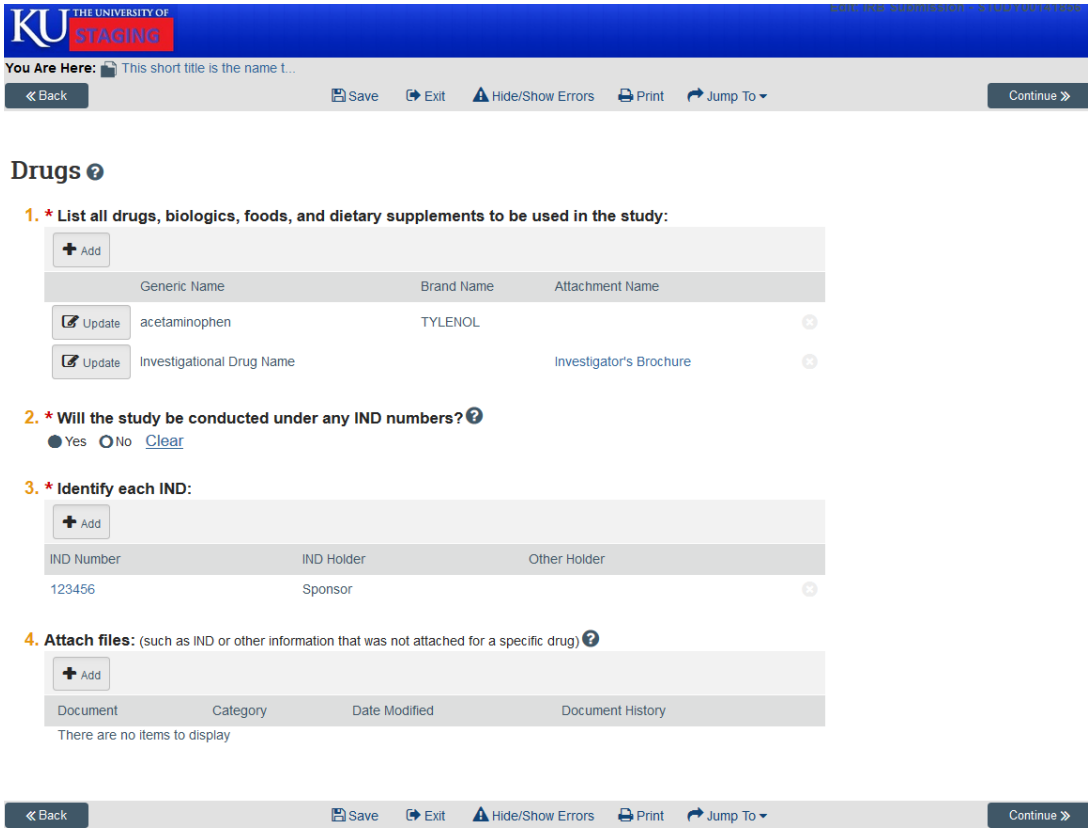
Research Locations (if applicable)

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

Drugs (if applicable)

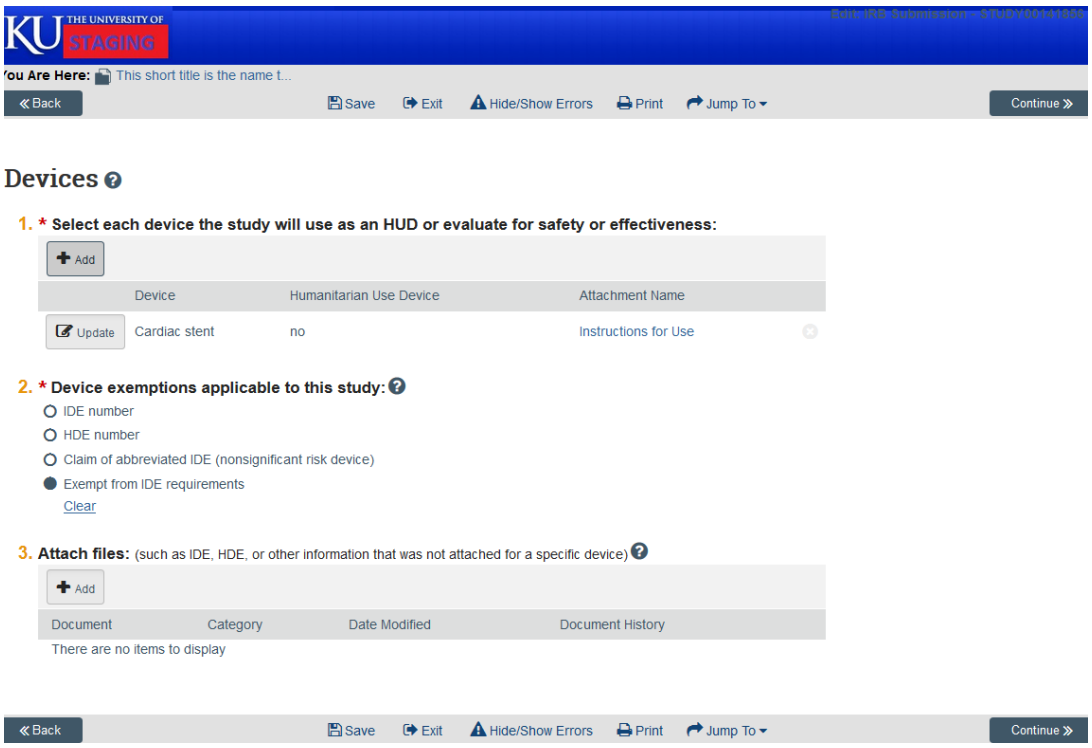
- Add each drug being used in the study.
- If you are using FDA-approved drugs, look on the first line of the secondary screen, which is auto-populated with drugs in the KU Hospital formulary.
- Investigational drugs are typed in by hand.
- Upload the investigator's brochure if applicable.
- Indicate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

(topic continued on next page)



<u>Devices</u> (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.



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:

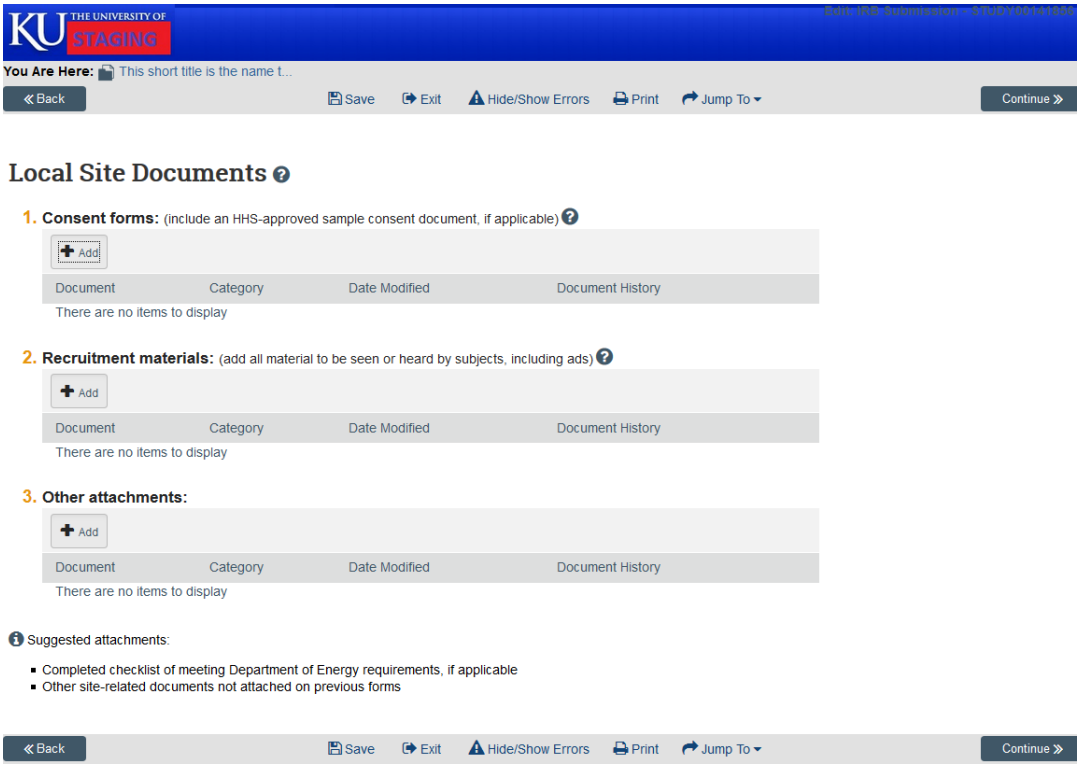
Notes:

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

Other attachments:

Notes:

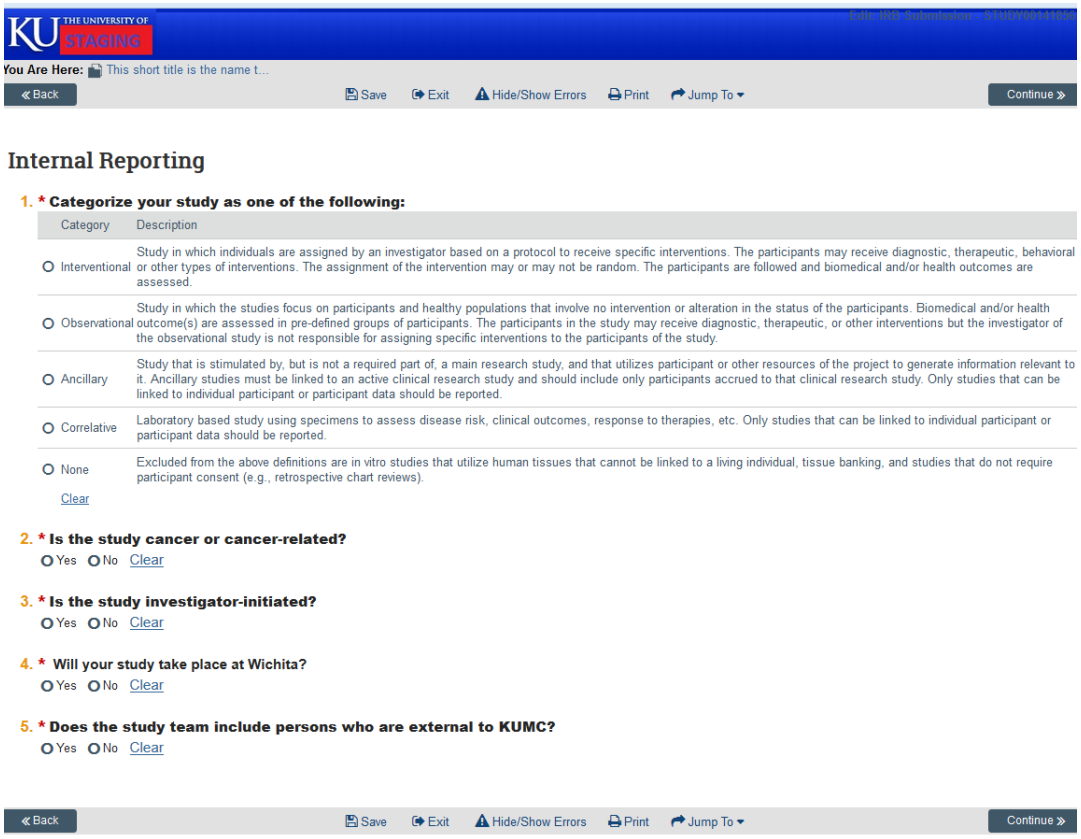
- Use this section to upload all other documents required for IRB review.
- Every initial submission will be accompanied by an appropriate Project Description, whether for Full Committee, Expedited, Exempt or Retrospective projects. The Project Description helps the IRB determine whether the proposal 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.



INTERNAL REPORTING

Notes:

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



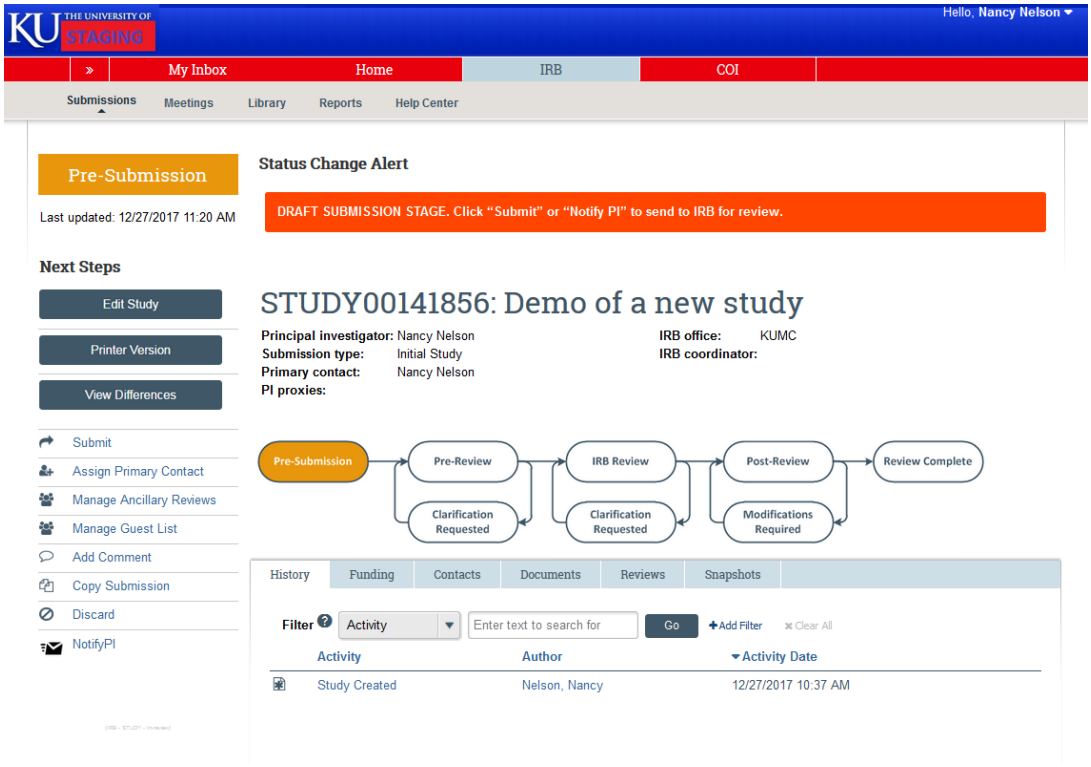
FINAL PAGE

Click Finish to save and exit the form.

MAIN STUDY PAGE

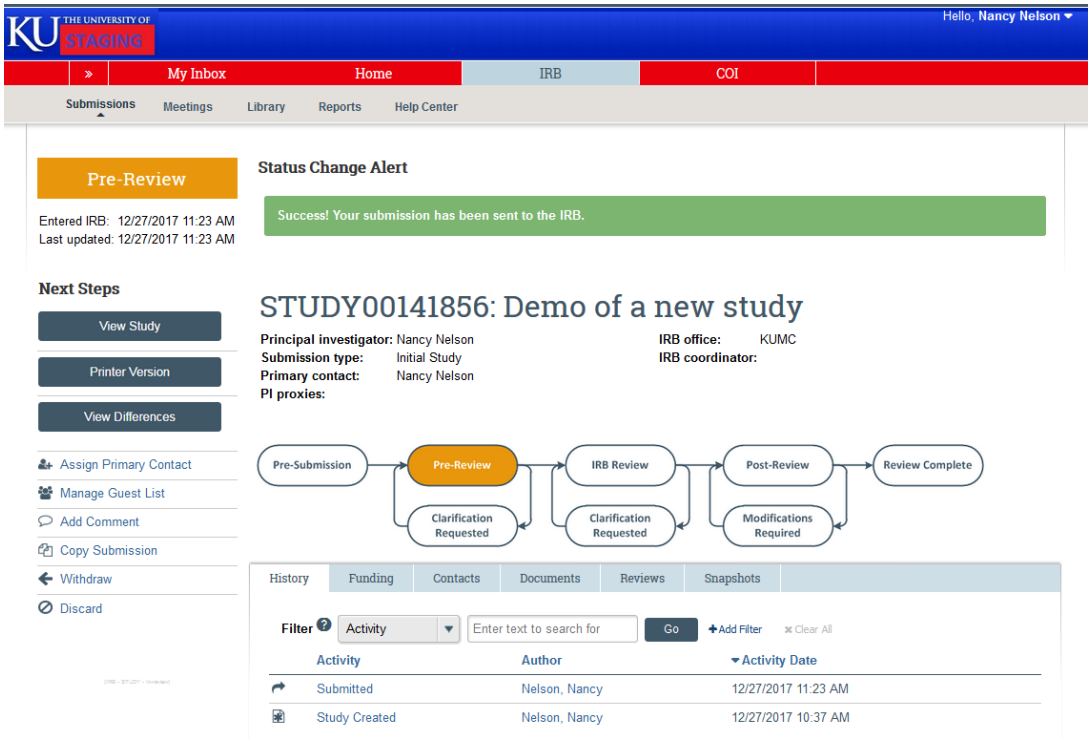
Now your study is created. Notice that the study is still in **Pre-Submission** status and has not been sent to the IRB. Both the yellow flow chart bubble and the yellow status bar indicate **Pre-Submission**. An orange **Draft Submission Stage** banner is also visible at the top of the page.

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**.



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.



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.

Checklist of Documents for Human Subjects Committee Application in eCompliance	
eCompliance Screen	**Documents to Prepare and Upload**
Basic Information	*Proposed study protocol
Funding Sources	Grant applications (if applicable)
Study Team Members	N/A
Study Scope	N/A
External Sites (if checked in Study Scope)	IRB Reliance letter (if available). Letter of support (if applicable)
Drugs (if checked in Study Scope)	For investigational drugs: Investigator's brochure, FDA letters (if applicable)
Devices (if checked in Study Scope)	Device Manual
Consent Form and Recruitment Materials	All proposed consent forms in Word only with no footer. All proposed recruitment materials
Internal Reporting	N/A
Supporting Documents	*Project Description for Full Committee Review, Exempt, Expedited, or Retrospective Studies If Applicable: • Scientific merit review • Surveys, instruments • Data collection sheet • DSMB or DMC Charter • Subject instructions, diaries, etc. • Ancillary approval letter (e.g., RSC, Nursing Impact, PRMC) • Sponsor correspondence • HIPAA waiver request
	***Required on all new studies**