myIRB guidance

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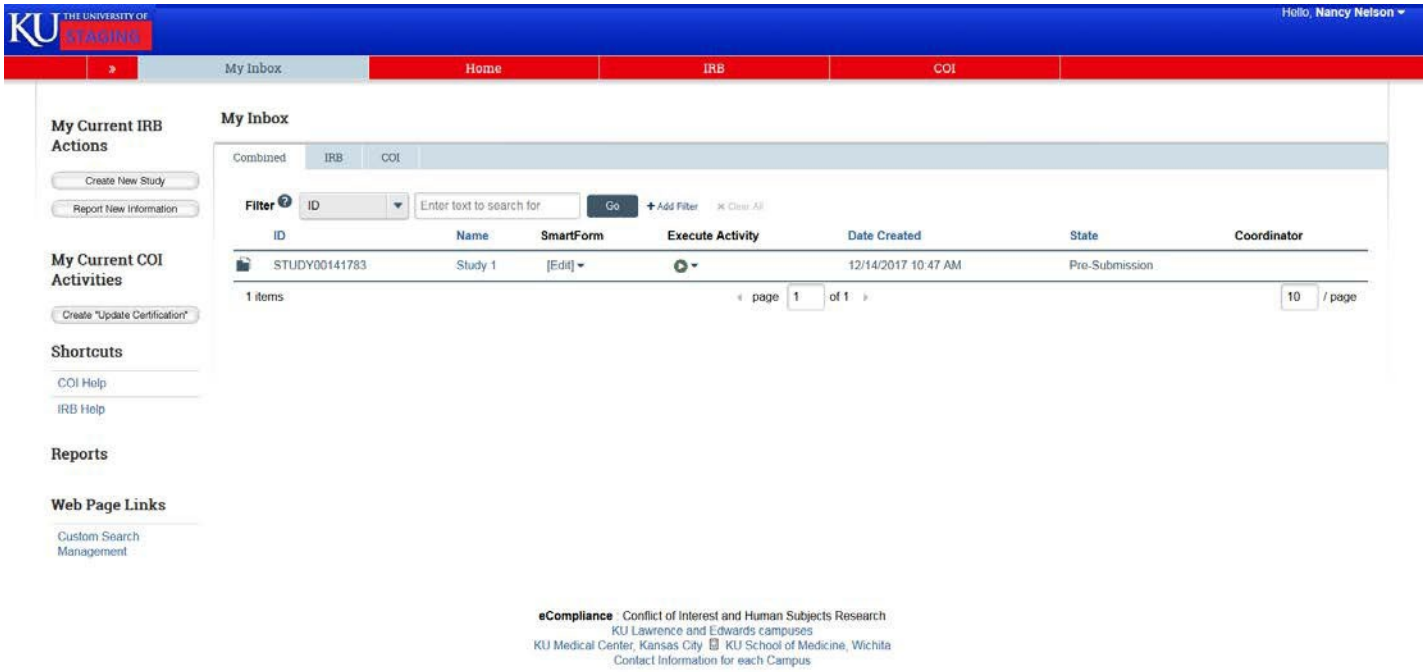
Required Documents for the KUMC myIRB Submission	
myIRB Screen	**Documents to Prepare and Upload**
Basic Information	*Proposed study protocol (or Protocol Application form for Secondary Research studies only)
Funding Sources	Grant applications (if applicable)
Study Team Members	N/A
Study Scope	N/A
Local Research Locations	Letters of support for external locations (if applicable) Communications with relying sites (if applicable)
Drugs (if checked in Study Scope)	• For investigational drugs: Investigator's brochure • FDA correspondence (if applicable) • Drug package insert, when an FDA-approved drug is being studied for an unapproved use
Devices (if checked in Study Scope)	Device Manual
Local Site Documents	*Project Description for Full Committee Review, Exempt, Expedited, or Flex Review Studies • Clean versions of proposed consent forms <u>in Word only with no footer</u>. • Proposed recruitment materials • PI Supplement (Full-Committee only) • IRB Checklist (Full-Committee only) • Lead Investigator Supplement (for Multi-site studies where KUMC is the Reviewing IRB) • Scientific merit review • Surveys, instruments • Data collection sheets • DSMB or DMC Charter • Subject instructions, diaries, etc. • Ancillary approval letter (e.g., RSC, Biosafety, PRMC) • Sponsor correspondence • HIPAA waiver request
Internal Reporting	N/A
	***Required on all new studies**

INVESTIGATOR GUIDANCE
Submitting a New Study in myIRB

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://kumcmyIRB.huronresearchsuite.com. 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**.

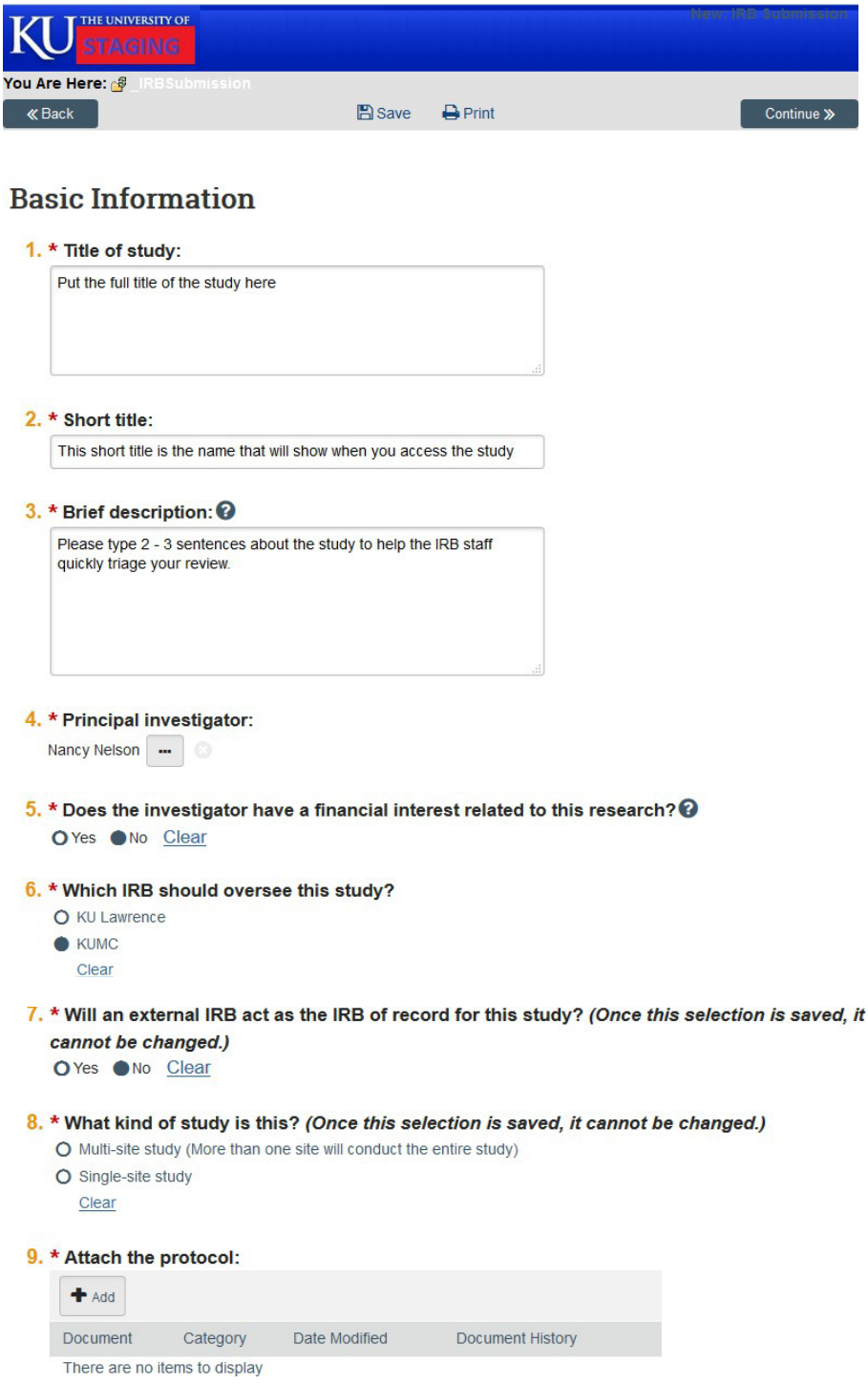


Once you select **Create New Study** you will be directed to the first of **9 required tabs.** As you complete the questions, you may also be prompted to answer questions on **3 additional tabs** relating to external research locations, drugs, and devices**,** if applicable to your study.

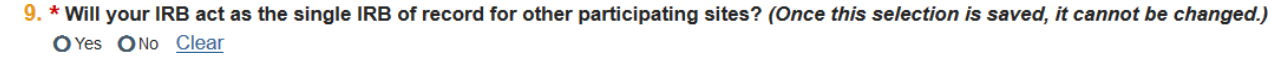
BASIC INFORMATION

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)



- 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.



- To attach the protocol, choose **Add** to upload your protocol.

FUNDING SOURCES

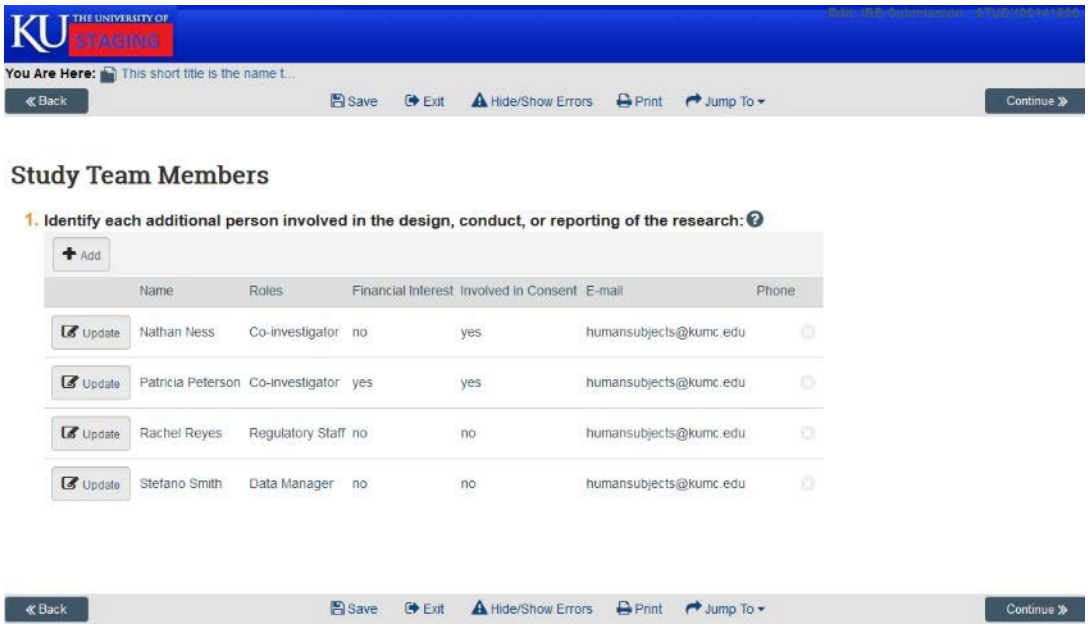
Notes:

- 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:

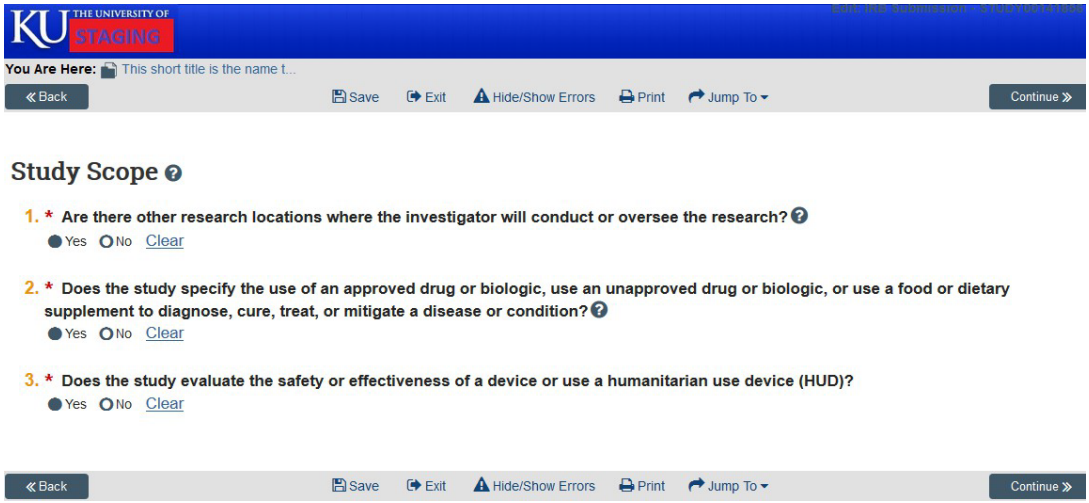
- Select your study team from the drop down list. All KUMC employees, residents and students have been populated to this list. Additionally, many KUH and UKP personnel have been added. KU Lawrence faculty also are listed.
- Contact the IRB office if you do not find an individual's name or if you are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



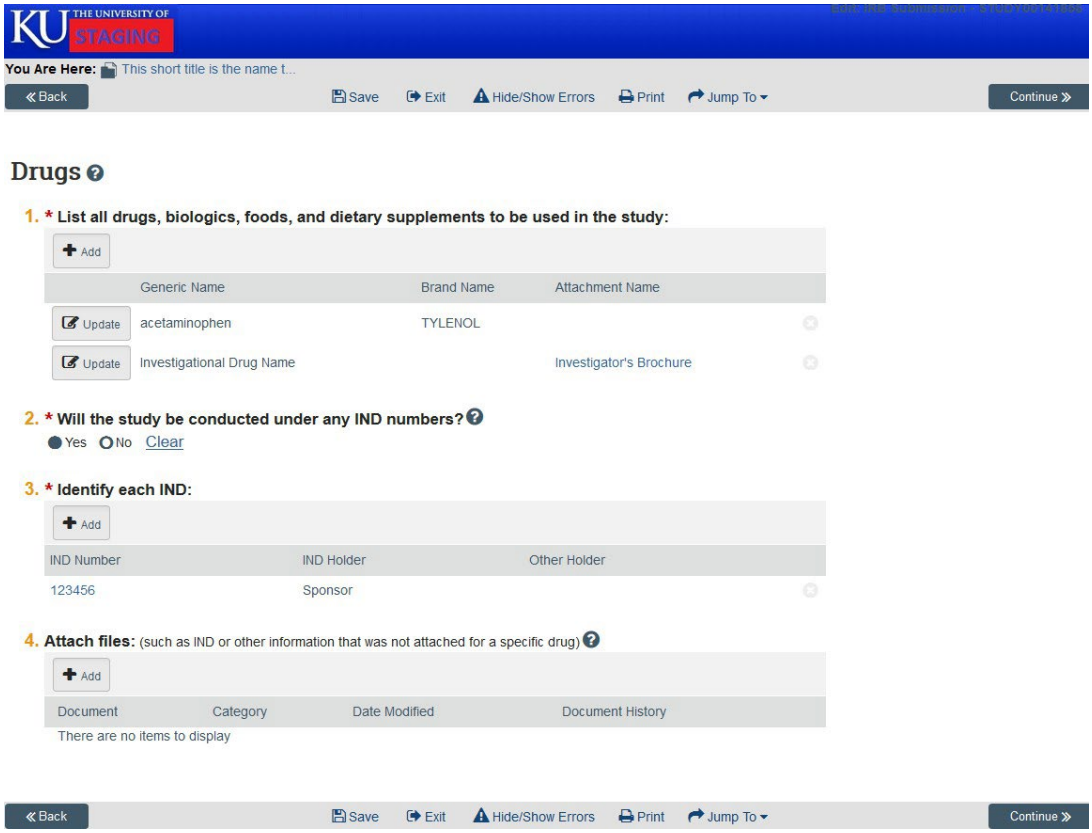
Research Locations (if applicable)

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

Drugs (if applicable)

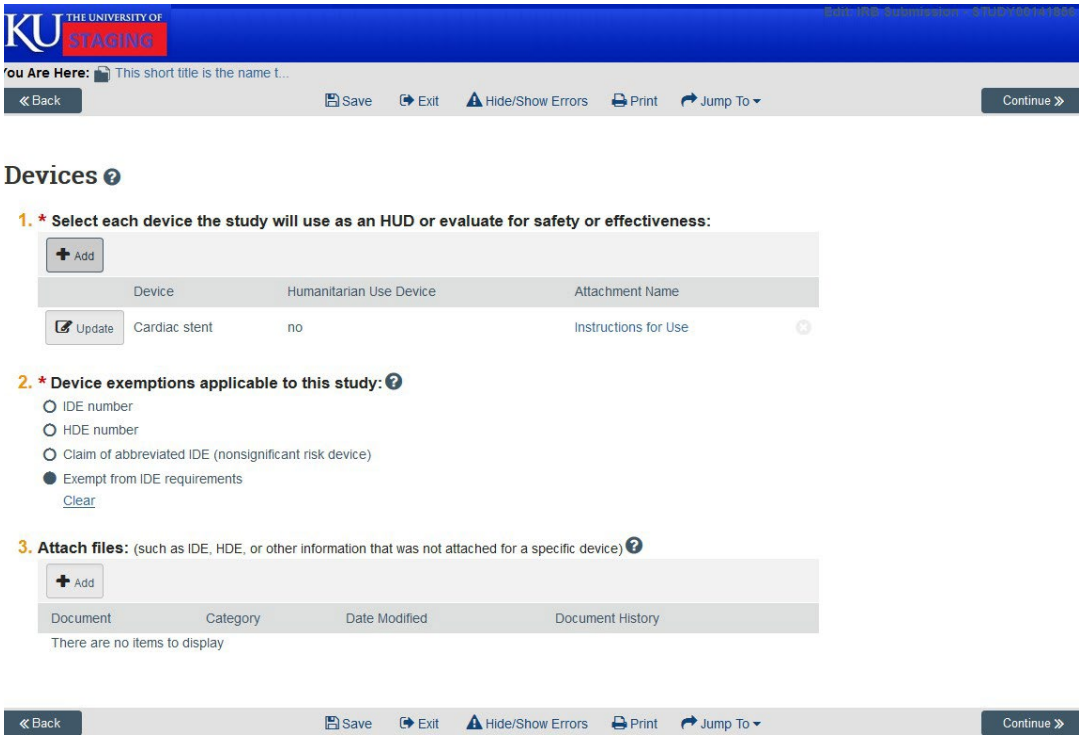
- Add each drug being used in the study.
- If you are using FDA-approved drugs, look on the first line of the secondary screen, which is auto-populated with drugs in the KU Hospital formulary.
- Investigational drugs are typed in by hand.
- Upload the investigator's brochure if applicable.
- Indicate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

(topic continued on next page)



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.



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:

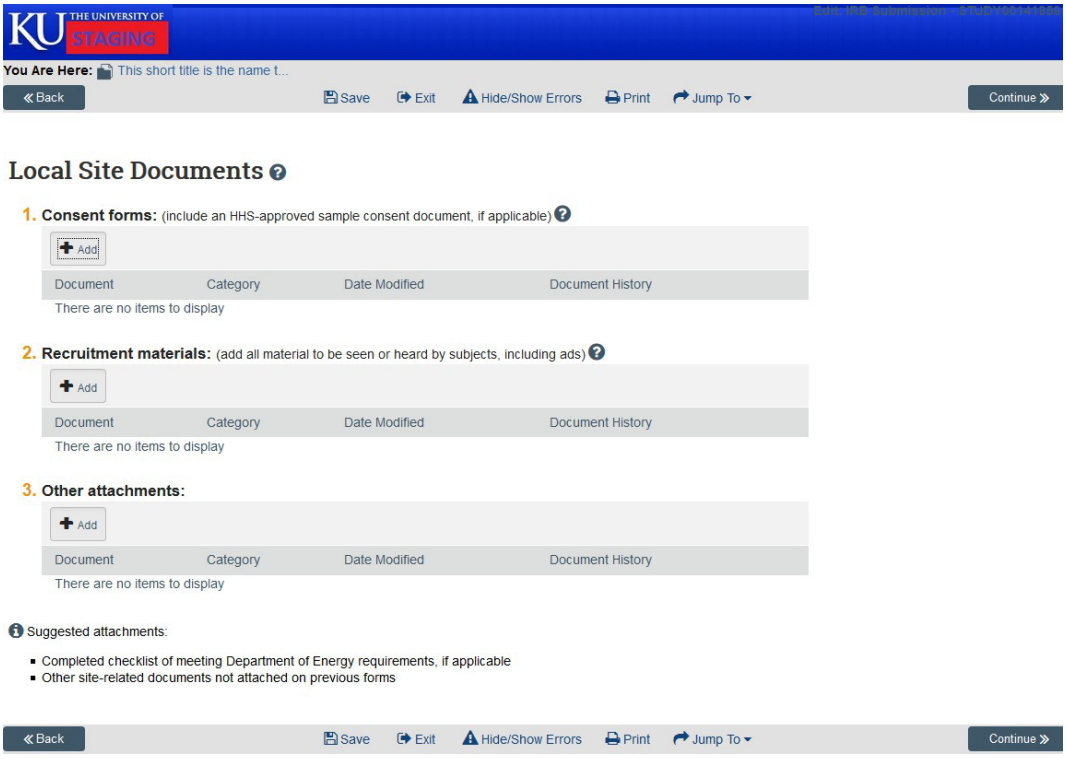
Notes:

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

Other attachments:

Notes:

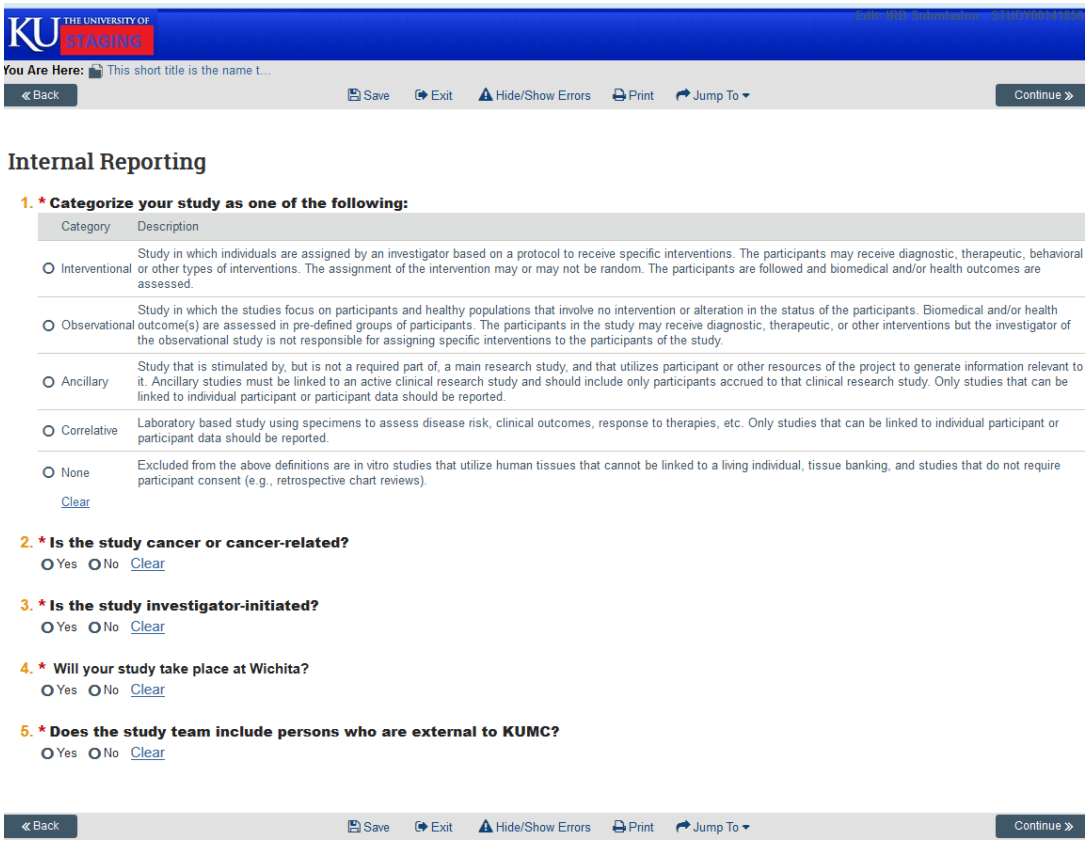
- Use this section to upload all other documents required for IRB review.
- Every initial submission will be accompanied by an appropriate Project Description, whether for Full Committee, Expedited, Exempt or Retrospective projects. The Project Description helps the IRB determine whether the proposal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



INTERNAL REPORTING

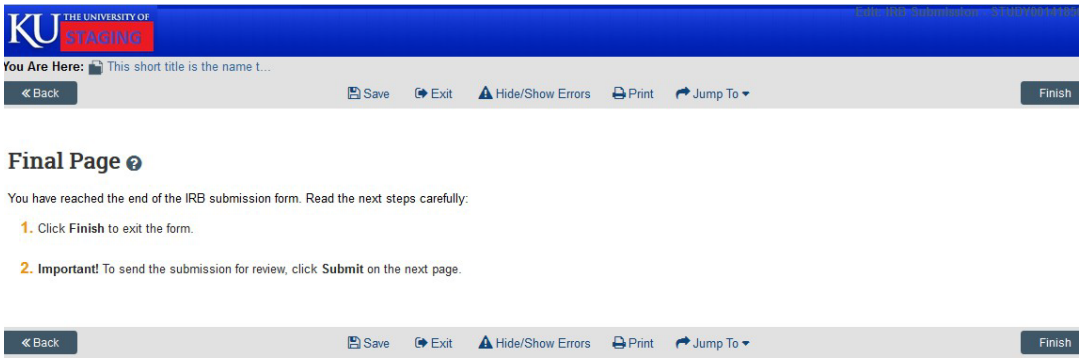
Notes:

- 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.

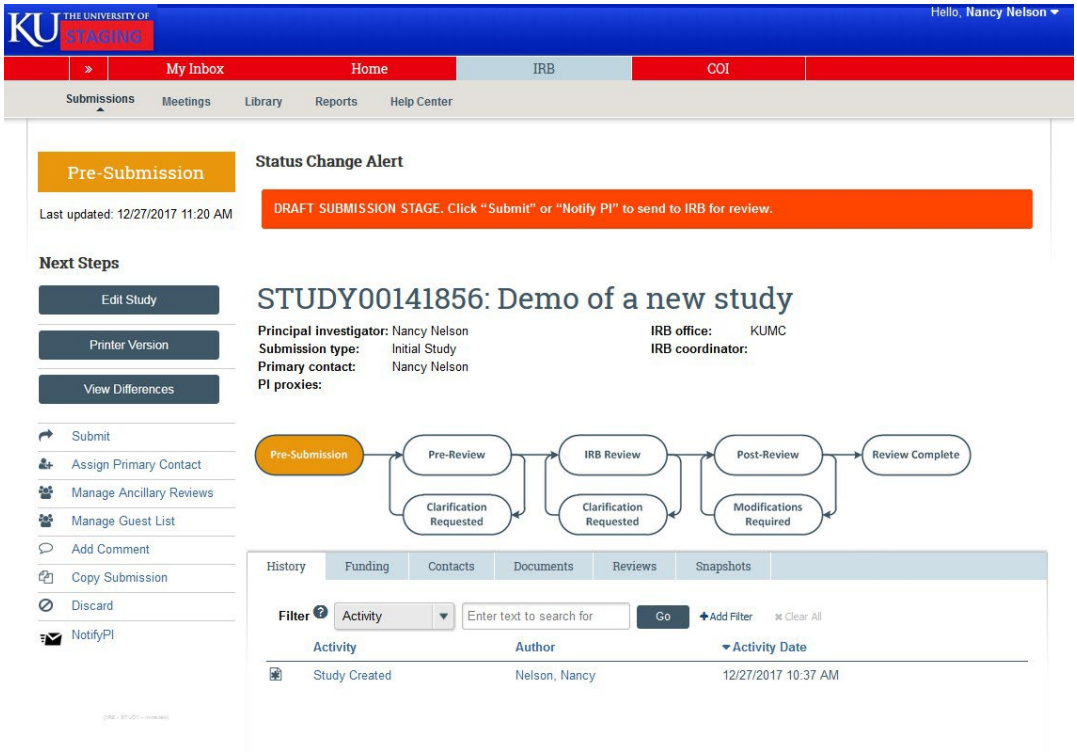


MAIN STUDY PAGE

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.

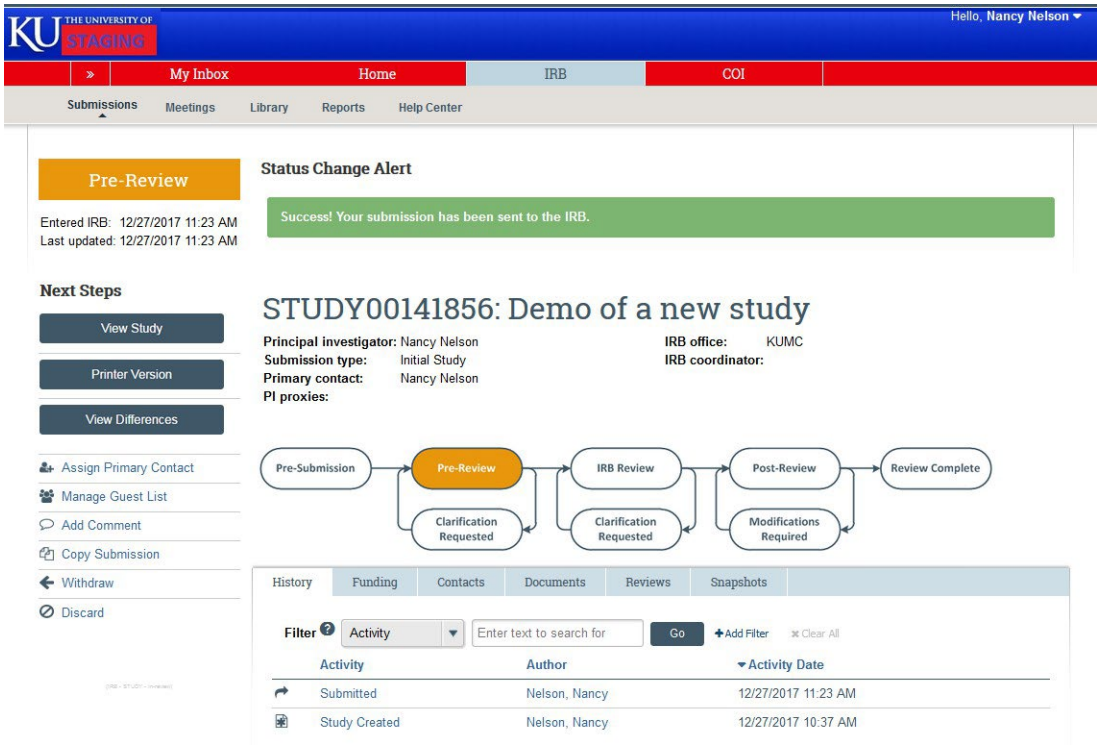
As long as the study is in Pre-Submission, the study can be edited by the PI or study team. The study stays in Pre-Submission until the PI hits the **Submit** button. Any member of the study team can create a study, but only the principal investigator has the **Submit** button.

Please email the PI to have them submit. The IRB staff find it is best practice to send the PI the URL for the submission so that they can log directly into the main page of the submission.



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**. 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.

PI Proxy for Electronic IRB submissions

The KUMC institutional review boards (IRBs) allow designated individuals to serve as "PI Proxy" for minor changes and updates to human subjects research that is managed through the electronic IRB system.

At any given time, one individual can be designated as the PI proxy.

Studies that are managed by the KUMC Research Institute or the University of Kansas Cancer Center may only have a proxy from those regulatory offices. For other studies, proxies must be a member of the study team, and the request must be submitted by the principal investigator.

If the principal investigator will be temporarily unavailable for an extended period, contact the IRB office about designating a sub-investigator as a proxy.

Proxy requests can be emailed to the IRB office at IRBhelp@kumc.edu

A PI proxy may submit the following items:

- Minor consent form changes on approved studies if the changes do not involve increased risk or changes to study design (e.g., small increase in payment; minor clarifications or corrections; new contact information)
- Proviso responses when the study has been conditionally approved. If the proxy submits the proviso response, the study team is responsible for maintaining documentation that the principal investigator has reviewed and approved the submission.
- Administrative or other minor changes to the protocol (e.g., editorial corrections; new sponsor contacts; additional questions or new versions of a previously-approved survey)
- Updated Investigator's Brochures that do not necessitate protocol or consent form changes
- Recruitment/retention materials
- Personnel changes, other than a change to the principal investigator
- Enrollment closures (Submitting a notice of enrollment closure is voluntary, but some sponsors request an IRB submission.)

If the IRB office determines the changes are not minor, the submission will be returned for PI submission.

The Principal Investigator must submit the following items:

- Initial submissions
- Proviso responses when the proposal is deferred
- Changes to the protocol or consent form that are being made because of new safety concerns, changes to study design, aims or methods or because of new risks
- Request for a change of PI. *This request must be accompanied by a written acknowledgement by the new PI.*
- Continuing Reviews
- Study Closure requests

Additionally, principal investigators will be asked to acknowledge their awareness when a Report of New Information (RNI) is referred to the convened committee for review. Convened committee review is required when an RNI indicates a new safety concern or serious non-compliance.

For questions about the PI Proxy policy, please contact your IRB office at 913-588-1240 (Kansas City) or 316-293-2610 (Wichita).

Quick Start / Reference Sheet

Answering Provisos in myIRB

Notification and Accessing the System

1. The eCompliance system will send a notification to investigators when the convened IRB or designated reviewer (for exempt and expedited studies) requires changes to the study prior to approval.
2. The Principal Investigator and the Primary Contact will receive an email that contains a link to the study workspace.
3. Log in using your KUMC Online ID and password.
4. You will see the following changes to the workspace:
    a. The study status has changed to **Modifications Required**.
    b. A proviso letter (**Correspondence**) is posted in the upper right corner under the study title.
    c. The **Edit Study** button is now available in the left column.

Provisos that Require Study Documents to be Added or Revised

1. Choose the **Edit Study** function on the left column
2. Use the "**Jump To**" option at the top of the screen to navigate to the tab that has the document(s) to be revised.
3. Choose the **Add** feature to add new documents that were not previously submitted. For example:
    a. On the Consent/ Recruitment tab, choose **Add** to submit a Tracked Changes version of the consent form.
    b. On the Supporting Documents tab, choose **Add** to submit a survey instrument or an approval letter from an ancillary review such as Radiation Safety Committee.
4. Choose the **Update** button to submit revised versions of your documents. For example, on the Consent/Recruitment tab, choose **Update** to attach a Clean Copy of a revised consent form. The original version will be replaced by the document you upload.

Provisos that Require a Narrative Answer

1. For brief responses: After you have made any changes to study documents (see above), type the response into the Notes Box that appears when you select **Submit Changes**. (Alternatively, you can download the optional **Supplement for Answering Provisos** from our website, and save it to your desktop or study folder, summarize all changes, and upload it to the Supporting Documents section.)
2. For longer narrative: Download the optional **Supplement for Answering Provisos** from our website and save it to your desktop or study folder. After you have made any changes to study documents, detail the changes on this supplement and upload it to the Supporting Documents section.

Submitting

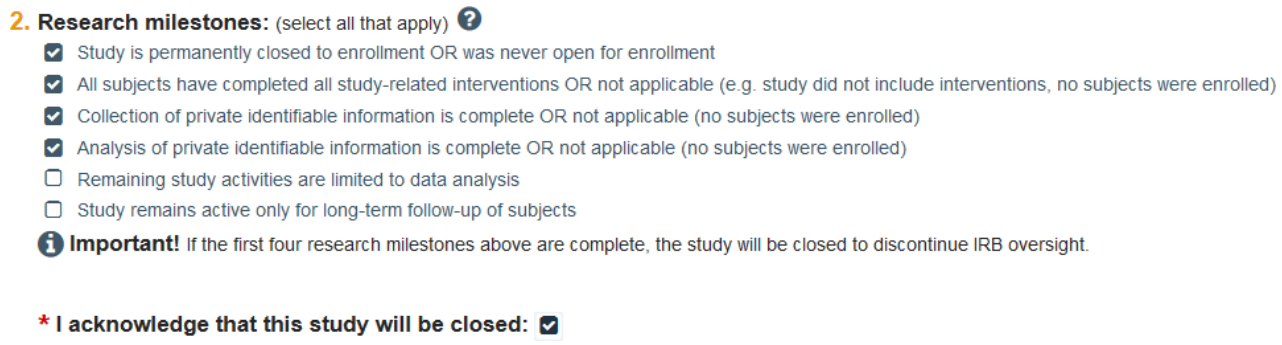
1. Select **Submit Changes,** attaching a response letter if desired. You will see the status change to "Post Review."
2. After the study is approved, it will appear in your "**Active**" tab of the IRB module. Your approved documents will appear as Finalized documents in the Documents section of the study workspace. Approved consent forms will be stamped with a footer that shows the approval and expiration dates.

Please feel free to call our office with questions: (913) 588-1240

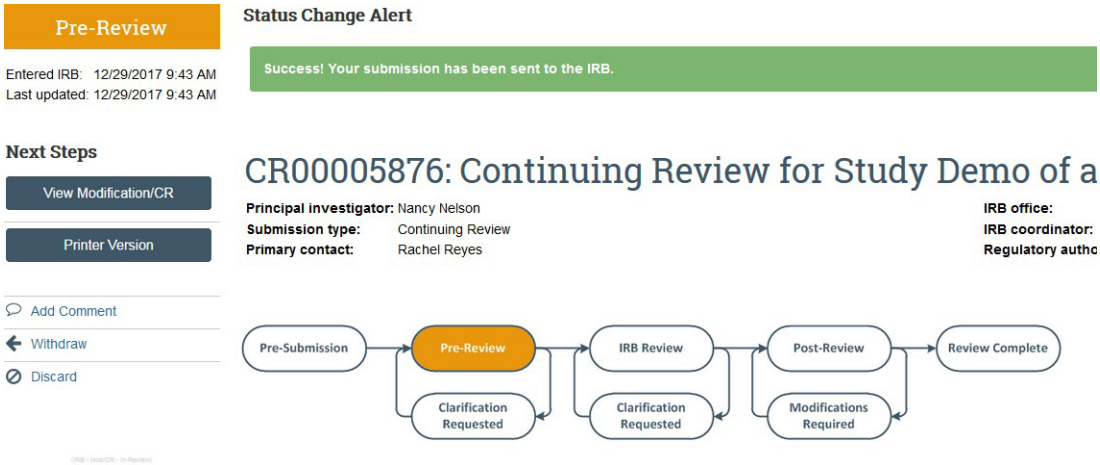
INVESTIGATOR GUIDANCE
Closing a Study in myIRB

In the myIRB system, study closures are submitted via the continuing review function. To create a study closure, select **Create Modification/CR** on the left of the main study workspace and then select **Continuing Review** as the purpose of the submission.

In order to close the study, the first **four** research milestones need to be selected, triggering the system to view the continuing review as a **study closure**. When the first four milestones are checked, a secondary checkbox will appear asking you to **acknowledge** that the study will be closed. Fill out the rest of the form as you normally would and then click **Continue** and **Finish**.



When you are ready to submit the closure, select the **Submit** action. Conversely, if you are not the PI, selecting **Notify PI** will alert them that the closure is ready for submission. A green status banner will confirm the successful submission of the study closure and both the yellow status bar and yellow flow chart bubble will transition to the **Pre-Review** state.



INVESTIGATOR GUIDANCE

Reviewing a Modification Created by Study Staff or Regulatory Staff

Study team members or regulatory staff can create modifications to existing studies on behalf of investigators.

The screen shots below demonstrate the **three steps** for investigators to (1) access the modification; (2) review the proposed changes; (3) submit to the IRB.

STEP 1: ACCESS THE PROPOSED MODIFICATION IN THE myIRB SYSTEM

When study staff or regulatory staff creates a modification on behalf of the investigator, the investigator will receive an email notification with the following message:

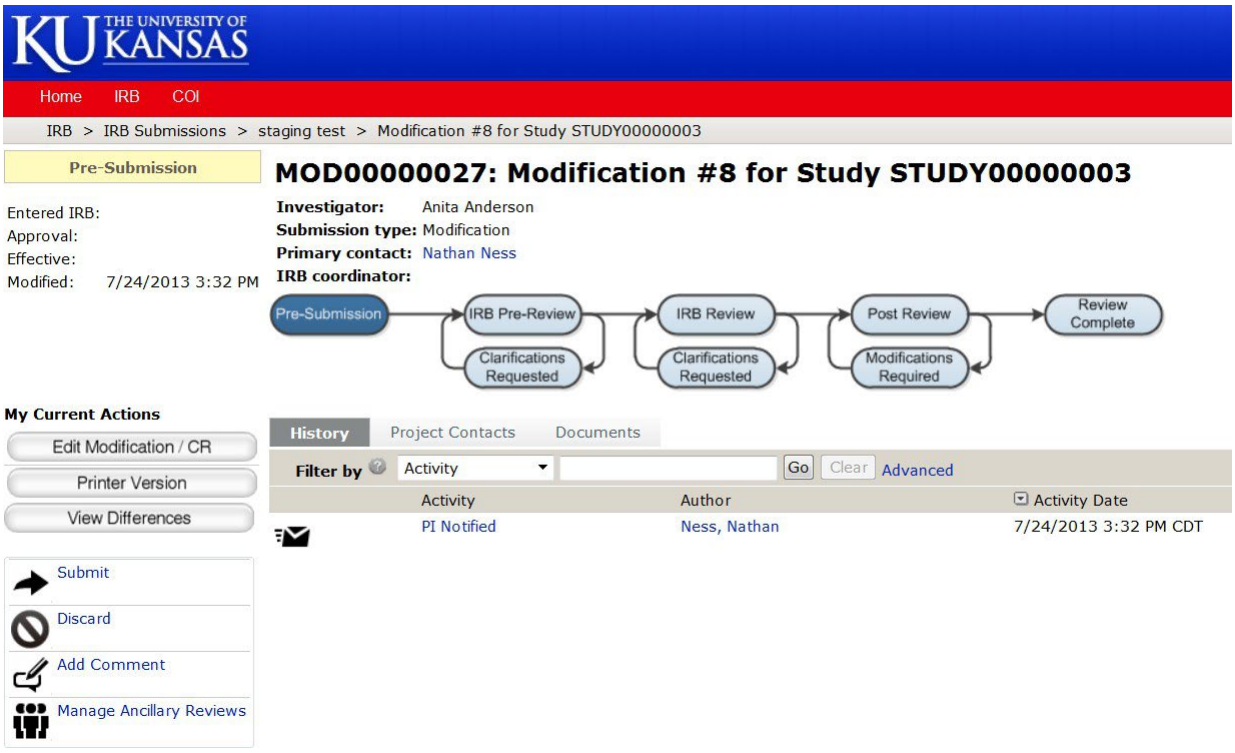
RE:	Notification to the PI
IRB Study ID#:	MOD000027
Study Title:	Modification #1 for Study 155555
Type of Submission:	Modification

Notification to the PI:

I have uploaded the revised investigator's brochure. I have also added David as the new study statistician.

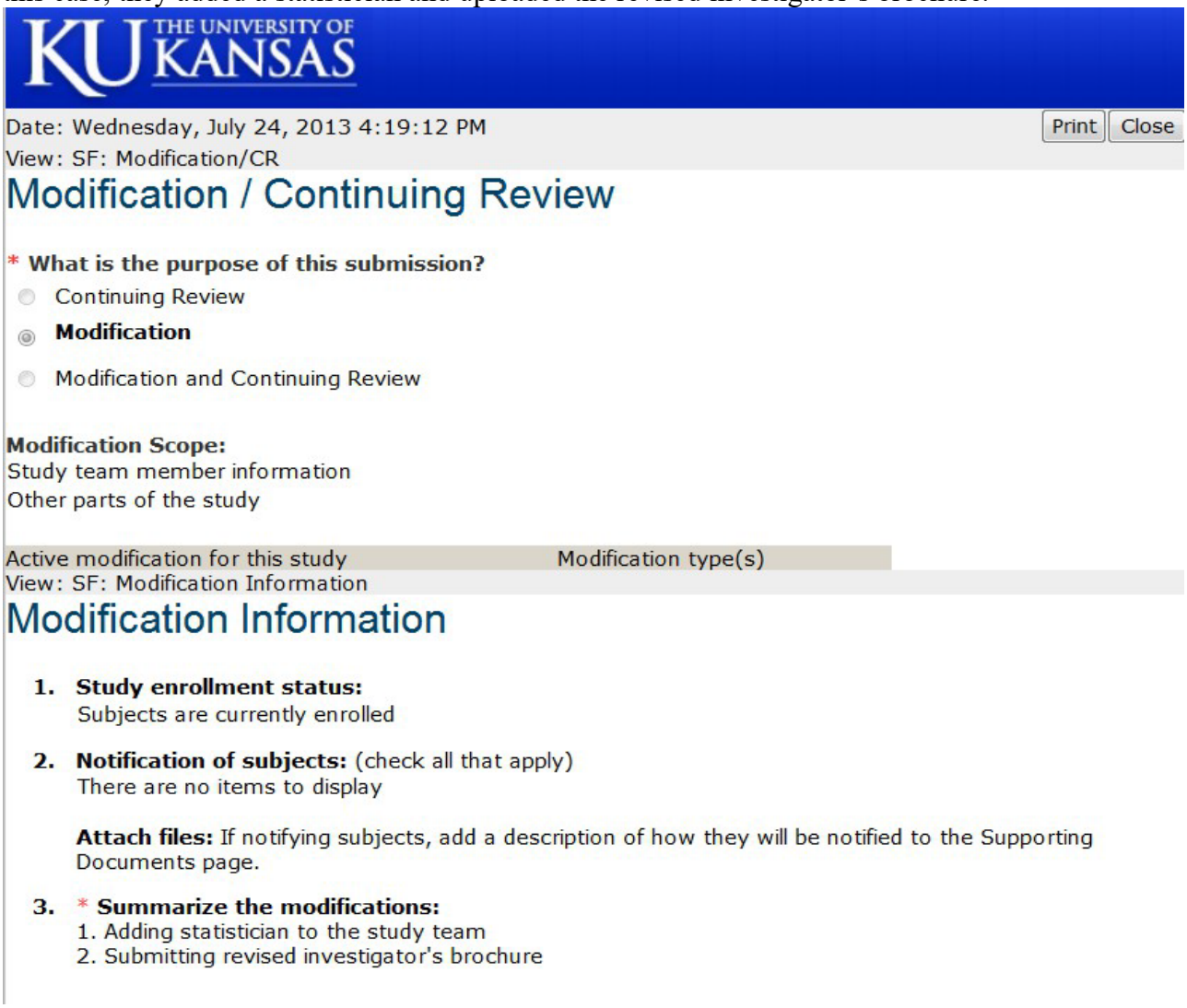
Thanks, Carol

When you click on the link in the email, you will be directed to the Log-in page for myIRB. Log in with your standard KUMC user name and password. You will see the modification screen with details about your study, shown in the following example. Notice that the modification is in a state of "Pre-Submission" because it has not been sent to the IRB.



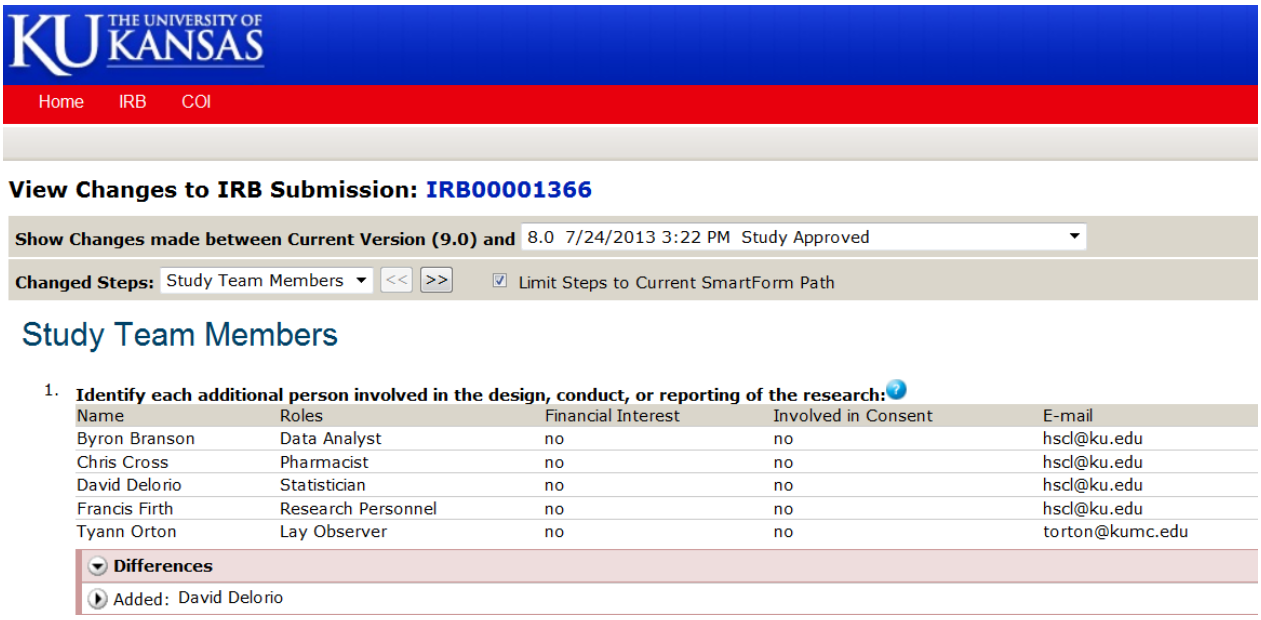
STEP 2: REVIEW THE PROPOSED CHANGES

If you select PRINTER VERSION in the modification screen shown above, you will see the following screenshot. It shows what the staff member entered to summarize the modification. In this case, they added a statistician and uploaded the revised investigator's brochure.



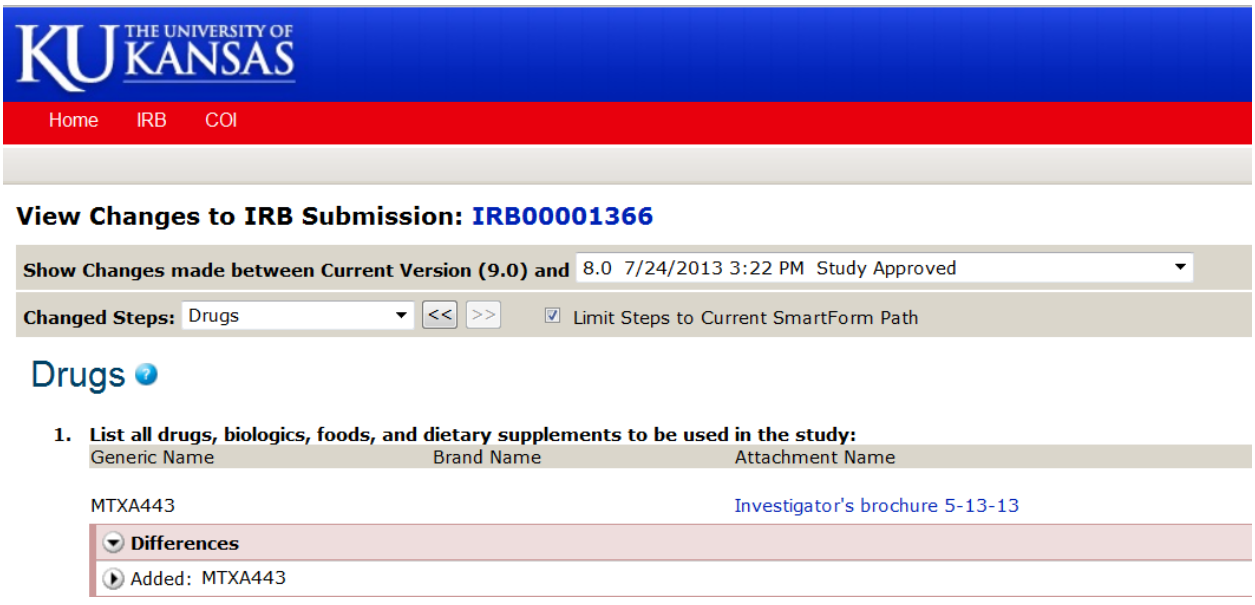
Hit "Close" to go back to the modification screen.

You can also select VIEW DIFFERENCES from the modification screen. View Differences will take you to the first tab of the study that was changed. The differences are shown in **GREY.** The screen below shows the new study team member that was added.



If more than one tab was changed, Access the "Changed Steps" box. The Changed Steps box appears in both the top and bottom of the screen, in Grey. It will give you a drop down list of all the areas of the study that were modified.

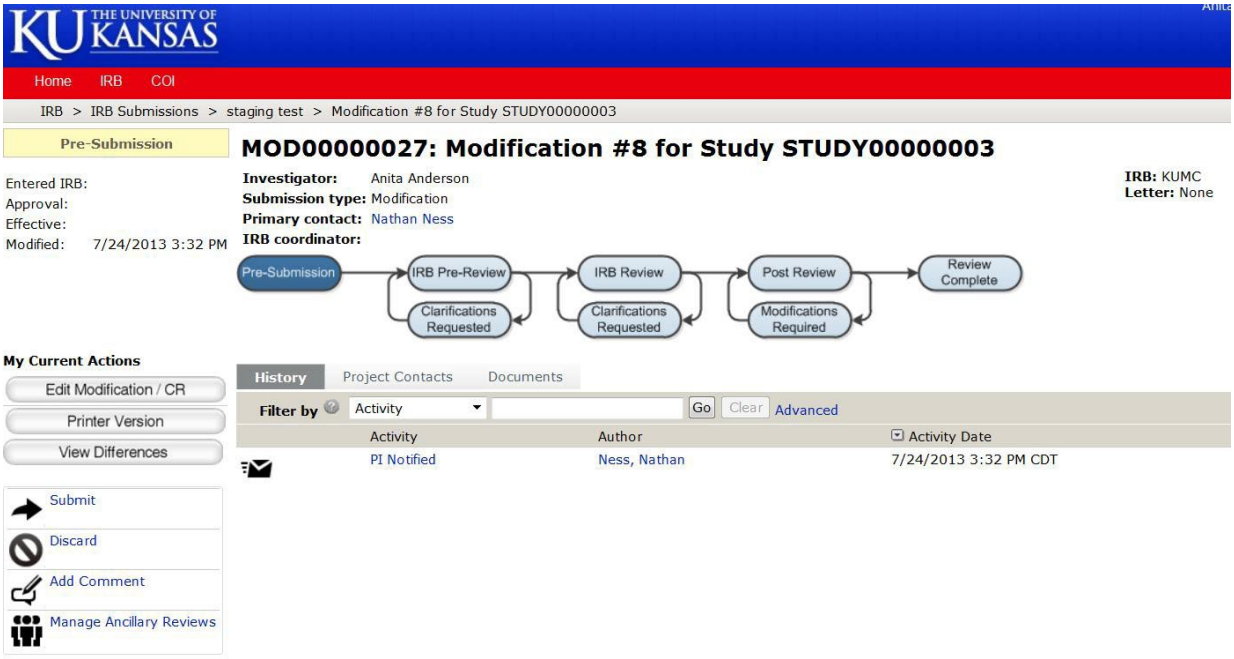
The screen below shows you that a new drug was added to the drug list and the Investigator's brochure was attached. You can click the link to open and read the investigator's brochure.



Once you click through all the Changed Steps, you CLOSE the view and return to the main page.

STEP 3: SUBMIT THE MODIFICATION TO THE IRB

Back on the modification screen, you have the option to select Edit Modification and make additional changes yourself, if needed. If everything is correct, hit SUBMIT to send the proposal to the IRB.



INVESTIGATOR GUIDANCE

Submitting a "Request for External IRB" Study in myIRB

The eCompliance software allows you to prepare your study documents in advance and then upload them for electronic review. Please refer to the "Submitting a New Study in eCompliance" guide if you need assistance with any of these pages.

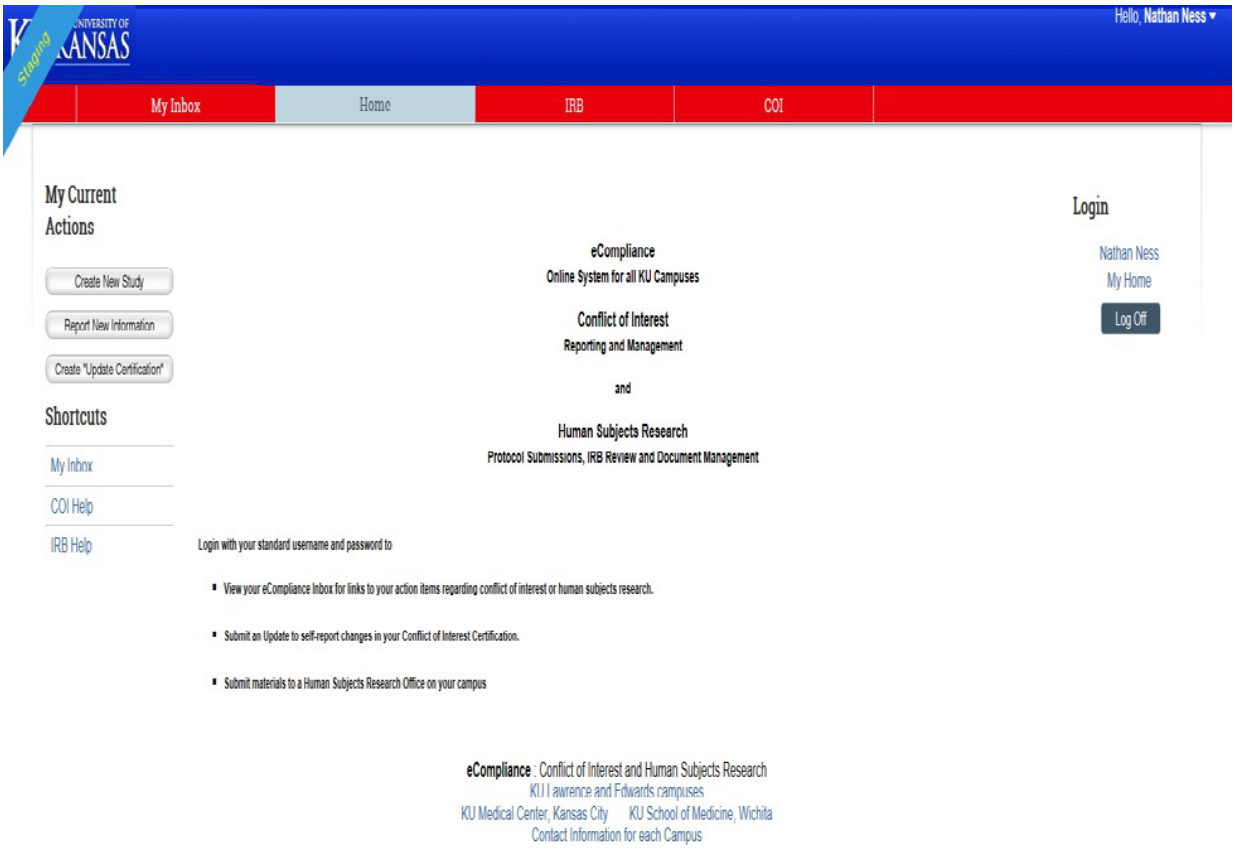
Start your electronic submission by logging in to the Home Page at: https://kumcmyIRB.huronresearchsuite.com.

On the right where it asks you to "Login" enter your regular KUMC email user name and password.

You should now see your personalized **Home Page**.

On the left you will notice a button to **"Create New Study"**. Click on this button.

(The picture below is from a test account)



Once you click “Create New Study” you will be directed to complete **“Basic Study Information”**.

BASIC STUDY INFORMATION

Notes for completing this section:

- For Item #2, the “Short Title” is how the study is referenced throughout the system. It needs to be less than 50 characters.
- For Item #4, select **Single-site study. (T**his must always be chosen)
- For Item #5, select **Yes**
- For Item #8, select **KUMC.** (Consult the IRB office for further instructions if the study will be conducted on the Lawrence campus).
- For Item #9, choose **“Add”** to upload the most current version of the **Protocol**

Basic Study Information

1. * **Title of study:**

Test Study 3-Not a Real Study

2. * **Short title:**

This is Test Study 3

3. * **Brief description:**

This is another test study.

4. * **What kind of study is this?**

○ Multi-site or Collaborative study

● Single-site study

Clear

5. * **Will an external IRB act as the IRB of record for this study?**

● Yes ○ No Clear

6. * **Local principal investigator:**

Nathan Ness ...

7. * **Does the local principal investigator have a financial interest related to this research?**

○ Yes ● No Clear

8. * **Which IRB should oversee this study?**

○ KU Lawrence

● KUMC

Clear

9. **Attach the protocol:**

+ Add

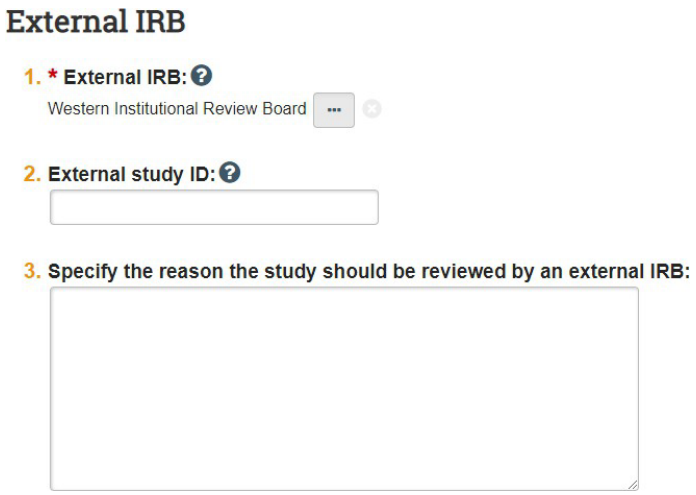
	Document	Category	Date Modified	Document History
Update	TEST PROTOCOL.doc(0.01)	IRB Protocol	8/8/2019	History

Because you indicated in Item #5 that an external IRB will act as the IRB of record for this study; completing external IRB information is required.

EXTERNAL IRB

Notes for completing this section:

- For item #1, select the External IRB from the list. If the External IRB is not listed, please contact the IRB office.
- Item #3 is usually answered “Sponsor Request”.



STUDY FUNDING SOURCES

Notes for completing this section:

- Choose “Add” to go to a drop-down list of sponsors.
- The drop-down list is auto-populated with all 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. Please upload the grant document on this page.
- You may hit “Continue” and skip this tab if your study is not funded.

Study Funding Sources

1. Identify each organization supplying funding for the study:

Add

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

STUDY TEAM MEMBERS

Notes for completing this section:

- 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 members are also listed. All key people working on the study need to be included as study personnel.
- Contact the IRB office if you do not find an individual's name. 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:

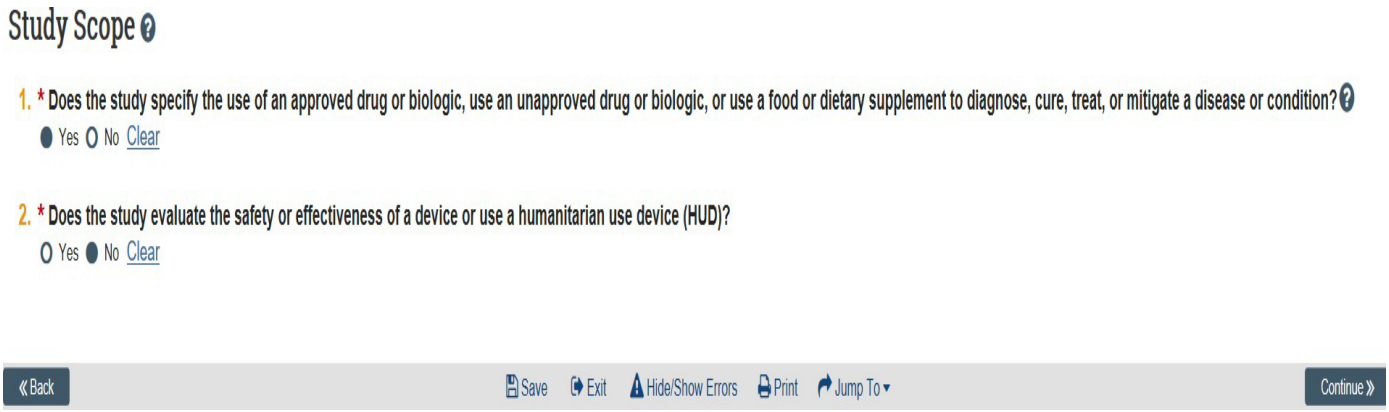
Add

	Name	Roles	Financial Interest	Involved in Consent	E-mail	Phone
Update	Natalie Norwood	Co-investigator	no	yes	humansubjects@kumc.edu	
Update	Rachel Reyes	Regulatory Staff	no	no	humansubjects@kumc.edu	
Update	Sandy Sorrenson	Study Coordinator	no	yes	humansubjects@kumc.edu	

STUDY SCOPE

Notes for completing this section:

- This page has branching logic on both questions. If your study involves drugs or devices, you will answer "yes" to the appropriate question and then provide details after the Local Research Locations Section.



LOCAL RESEARCH LOCATIONS

Notes for completing this section:

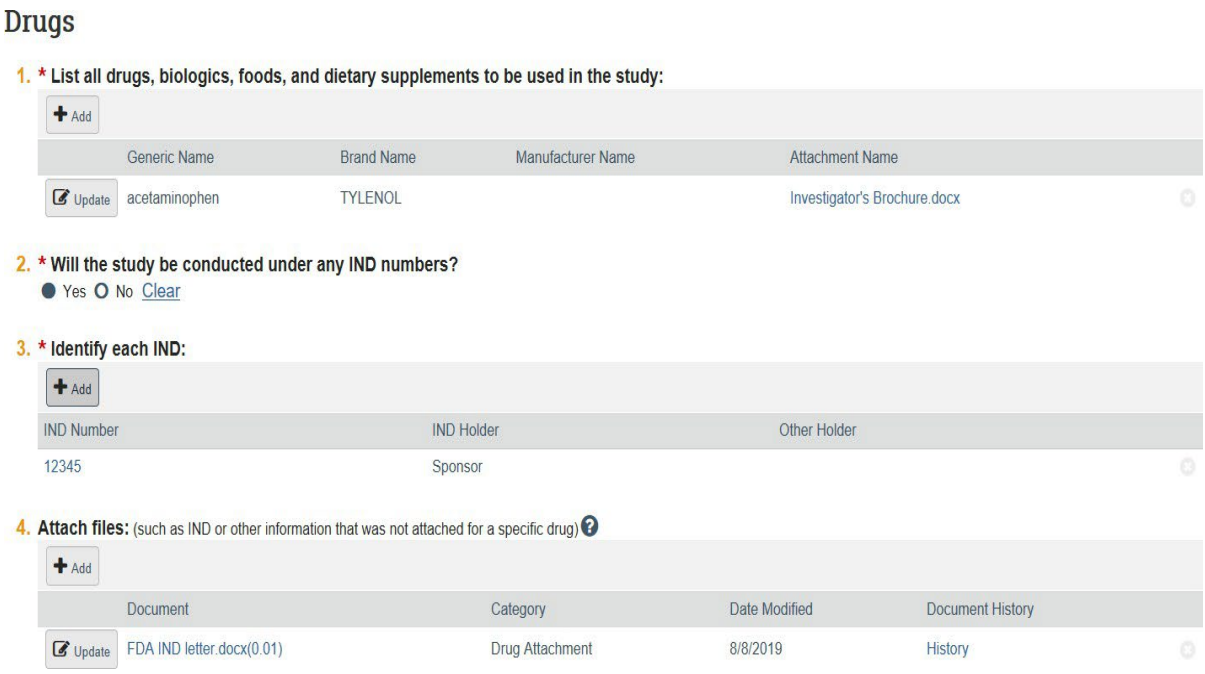
- Add all research locations (other than KUMC) and their contacts.
- Contact the IRB office if you have questions about this section.

If you checked “yes” for Item #1 in the Study Scope Section, you will complete a “Drugs” section.

DRUGS

Notes for completing this section:

- For #1, click “Add” and a box will show up to “Add Drug Information”. Select the study drug from the list. If the study drug is not listed, enter the generic name or brand name where indicated and attach the Investigator Brochure or Package Insert related to the study drug. If the study is using more than one drug list them each in this section.
- For #2 and #3, if the answer is “yes” for #2 then click “Add” in #3 and enter the IND number. This is found on the FDA IND letter provided by the Sponsor or on page 1 of the Protocol. Also indicate who holds the IND.
- For #4, click “Add” to attach the FDA IND letter.

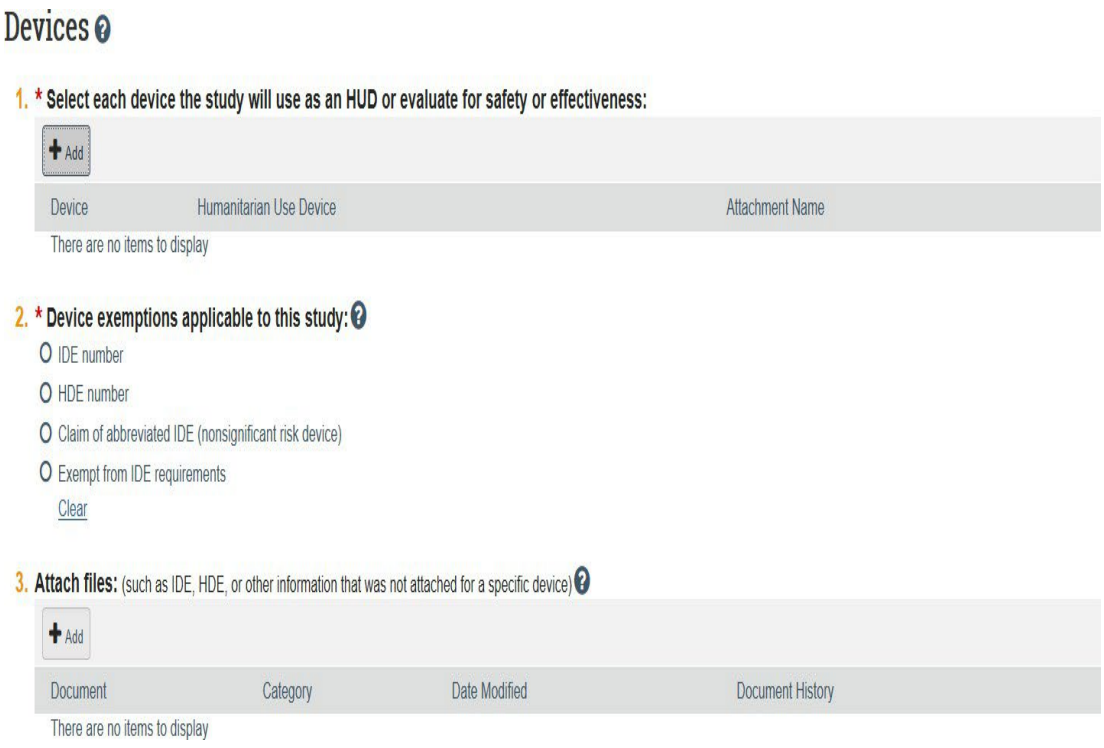


If you checked “yes” for Item #2 in the Study Scope Section, you will complete a “Devices” section.

DEVICES

Notes for completing this section:

- For #1, click “Add” and a box will show up to “Add Device Information”. Select the device from the list. If the device is not listed, enter the device name where indicated. Indicate if this is a Humanitarian use device or not (HUD).
- For #3, click “Add” to attach product instructions, IDE information, or HDE information.



LOCAL SITE DOCUMENTS

For External IRB forms please visit https://www.kumc.edu/research/research-administration/institutional-review-board/forms-templates-and-resources/forms-and-templates.html

Consent forms:

Upload:

- The External IRB approved consent form (usually has an IRB stamp or footer)
- The proposed KUMC consent form draft(s) with tracked changes. (Create this by customizing the External IRB approved consent form with site-specific verbiage regarding PI name and contact information, local payment information/ClinCard information, cost language, injury language, and adding KUMC entities in the HIPAA section).
- Please refer to the "External IRB Guidance" document on the IRB website when adding KUMC language to external consent templates. This can be found by clicking "IRB Reliance Resources" then "Reliance Forms, Templates, And Guidance" then "Instructions for Non-Commercial External IRBs".
- Western IRB and Advarra IRB approved consent templates have specifically negotiated boilerplate KUMC language to be added. Specific instructions are required to follow because the information has already been separately negotiated. These instructions are located on the IRB website under "IRB Reliance Resources" then click "Reliance Forms, Templates, And Guidance".
- If you have any questions, please contact the IRB office for help.

Recruitment materials:

- Upload any KUMC-specific recruitment materials that will be used by the KUMC investigators.

Other attachments:

This section is for all other documents required for KUMC local context review.
Please classify documents by applicable category.

Upload:

- Every submission must include either the:
  - ✓ Generic **Request to Use an External IRB** form, OR, the
  - ✓ CTSA **Partners Request for Single IRB Review** form (for research involving CTSA regional partners such as CMH, St. Luke's, Truman, UMKC, and KCUMB)
- **PRMC Approval** (for cancer studies only)
- **Radiation Safety or Information Safety Approval** (if applicable to the study)

Local Site Documents

1. **Consent forms:** (include an HHS-approved sample consent document, if applicable)

Add

	Document	Category	Date Modified	Document History
Update	Adult Consent Form_tracked(0.01)	Consent Form	8/9/2019	History
Update	WIRB-Approved Global Consent Template.docx(0.01)	Consent Form	8/8/2019	History

2. **Recruitment materials:** (add all material to be seen or heard by subjects, including ads)

Add

	Document	Category	Date Modified	Document History
Update	TEST ADVERTISEMENT.doc(0.01)	Recruitment Materials	8/8/2019	History

3. **Other attachments:**

Add

	Document	Category	Date Modified	Document History
Update	TEST DATA COLLECTION SHEET.doc(0.01)	Data Collection Sheet	8/8/2019	History
Update	Test Project description document.docx(0.01)	Supplemental Application Form	8/8/2019	History
Update	Ness SCIENTIFIC REVIEWER CHECKLIST.doc(0.01)	Scientific Merit Review	8/8/2019	History

Suggested attachments:

- Completed checklist of meeting Department of Energy requirements, if applicable
- Other site-related documents not attached on previous forms

INTERNAL REPORTING

Internal Reporting

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

Category	Description

- **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.

- **Observational**
  Study in which the focus is 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.

- **Ancillary**
  Study that is stimulated by, but is not a required part of, a main research study, and 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.

- **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.

- **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).

2. * **Is the study cancer or cancer-related?**
   ○ Yes ● No Clear

3. * **Is the study investigator-initiated?**
   ○ Yes ● No Clear

4. * **Is the study being conducted by KUSM-W faculty?**
   ○ Yes ● No Clear

5. * **Does the study team include persons who are external to KUMC?**
   ○ Yes ● No Clear

6. * **Is this trial listed on clinicaltrials.gov?**
   ● Yes ○ No Clear

   * **If yes, what is the clinicaltrials.gov number?**
   123454

FINAL PAGE

- Click “Finish” to save and exit the form.
- PLEASE NOTE that completing the Final Page does not send your study to the IRB. Please continue to the “Main Study Page” to complete the study submission process.

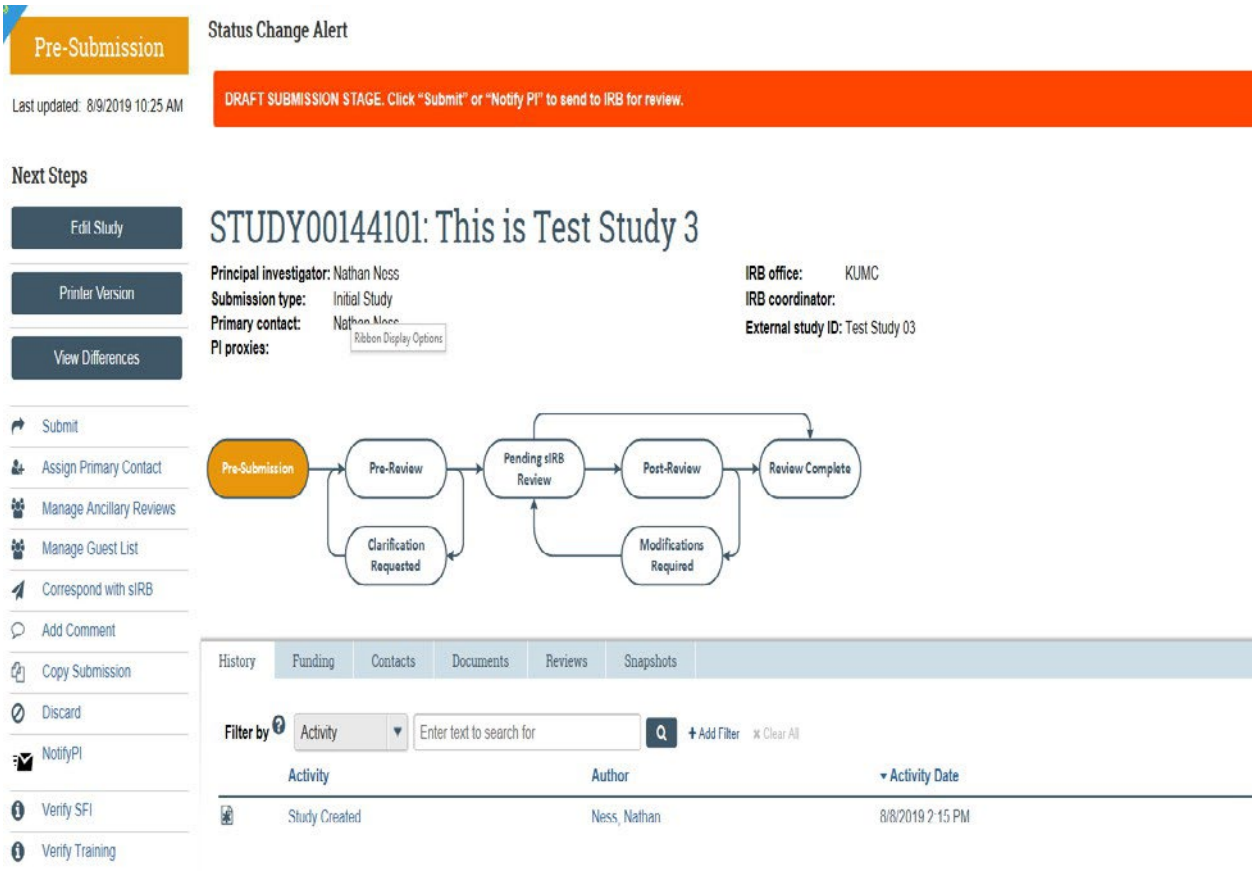
MAIN STUDY PAGE

Now the new study is created. The study has been issued a STUDY# that shows on this main page. Both the orange flow chart bubble and the orange status bar indicate “Pre-Submission” because the study has not been sent to the IRB yet.

As long as the study is in “Pre-Submission” it can be edited by the PI, study team, or Research Institute. The study stays in “Pre-Submission” until it has been submitted.

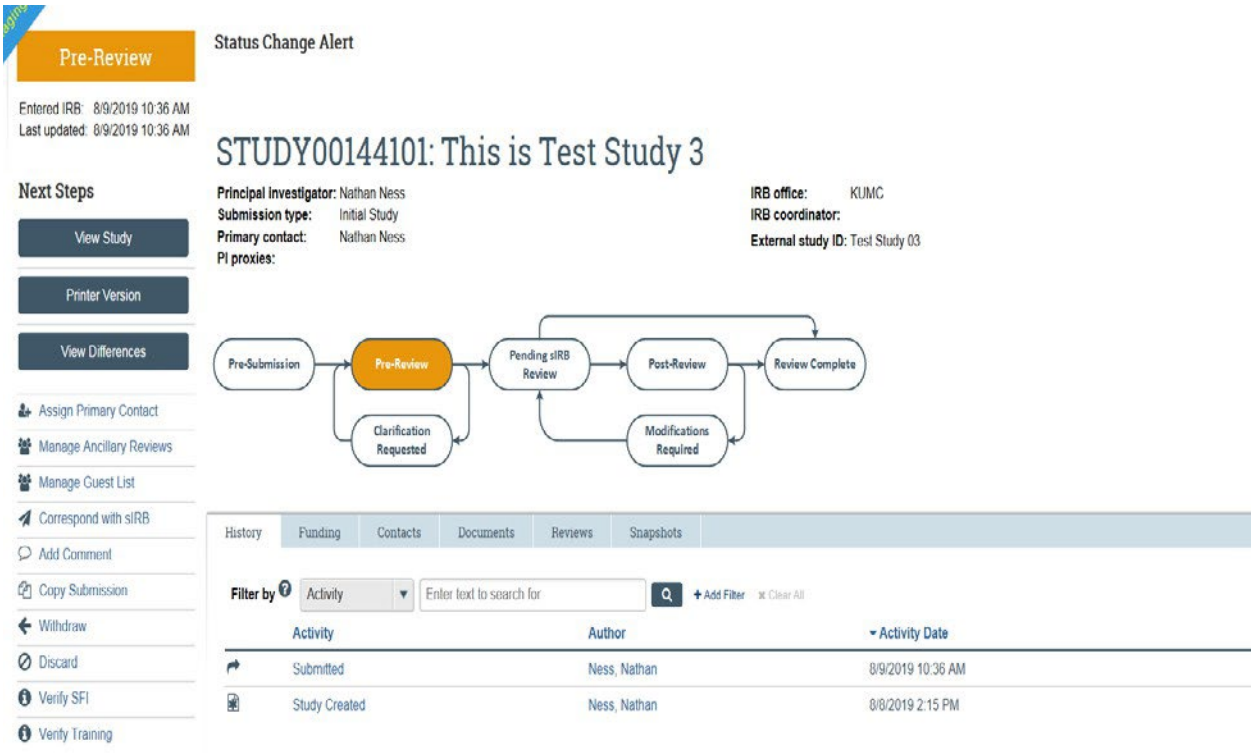
Any member of the study team or the Research Institute can create a new study, but only the PI can hit the “Submit” button to initially submit the new study.

Other study team members, or members of the Research Institute, the PI must be notified to “Submit” the study.



SUBMIT THE STUDY IN myIRB

Once the study is submitted by the PI, a green banner will temporarily flash across the top of the screen to confirm successful submission of the study. Both the orange flow chart bubble and the orange status bar will now indicate "Pre-Review". The Submission is now locked and the "Edit Study" button has been replaced with "View Study". The PI may add a comment with the submission that will be viewable by anyone who has access to the study.



SUBMISSION TO THE EXTERNAL IRB

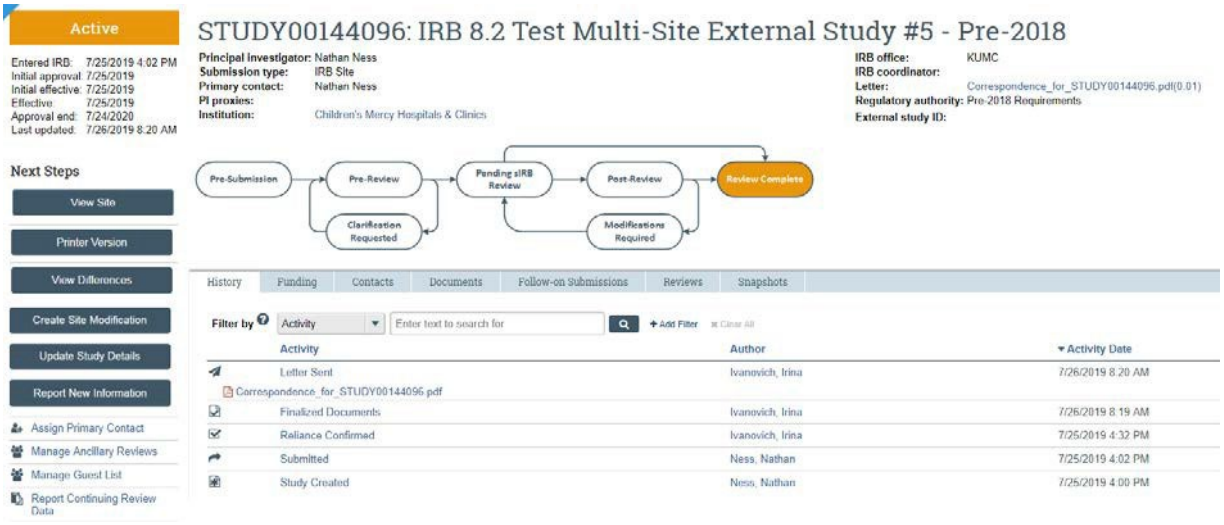
- Once the KUMC IRB staff members have finished their local review of the study materials and all ancillary reviews are completed you will be instructed to submit the KUMC documents to the External IRB.
- For Academic Institutions please coordinate this process with the lead contact at the External IRB.
- For reliance on commercial IRBs, follow the steps required for submission by those IRBs.
- Once you have received External IRB approval for KUMC to be a site, upload the External IRB documents in the “Local Site Documents” section in the myIRB system. The consent form will need to be added to the “Consent forms” section and the approval letter will need to be added to the “other attachments” section. Click “Submit Response” and send the study back for final acknowledgment.
- The IRB staff will generate an Acknowledgement of Protocol letter confirming that IRB approval is in place.

Updating a Study Relying on an External IRB

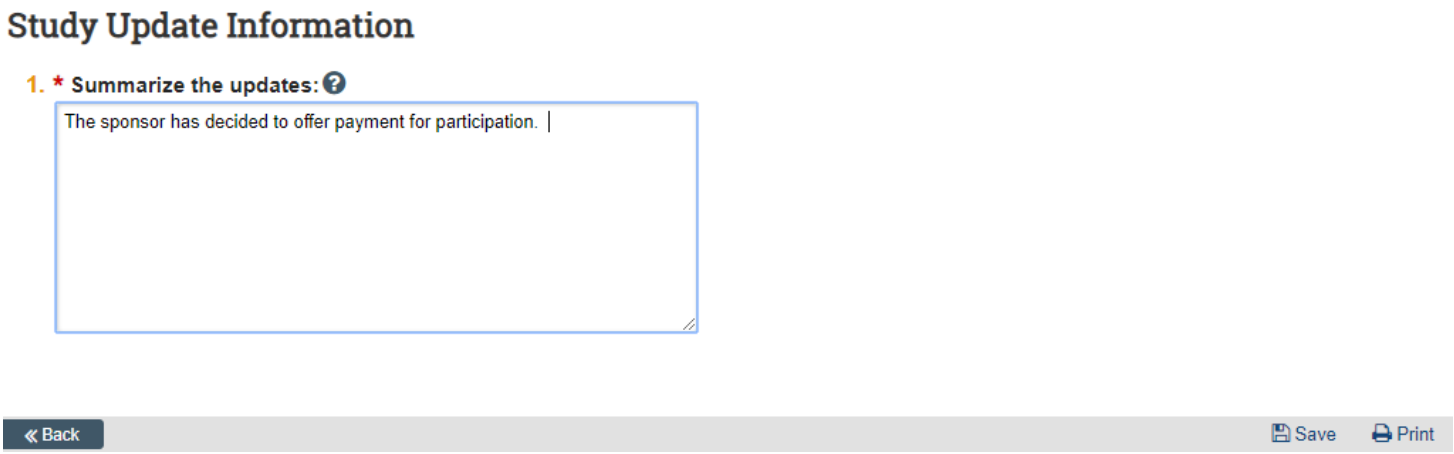
For studies under an external IRB, the external IRB is responsible for review of all protocol modifications, consent changes, recruitment materials and other study documents. In addition to working with the external IRB, study teams must inform the KUMC IRB if the following changes occur during the study:

- New KUMC principal investigator
- Changes to financial relationships that could create a conflict of interest for the study
- Contractual changes related to payment for study-related injury
- Changes impacting HIPAA privacy or data security
- Changes impacting costs
- New payments to participants if payments were not included in the original submission
- Internal serious adverse events
- Potentially serious issues of non-compliance
- Continuing Review Approval by the External IRB

1. Choose the **"Update Study Details"** button

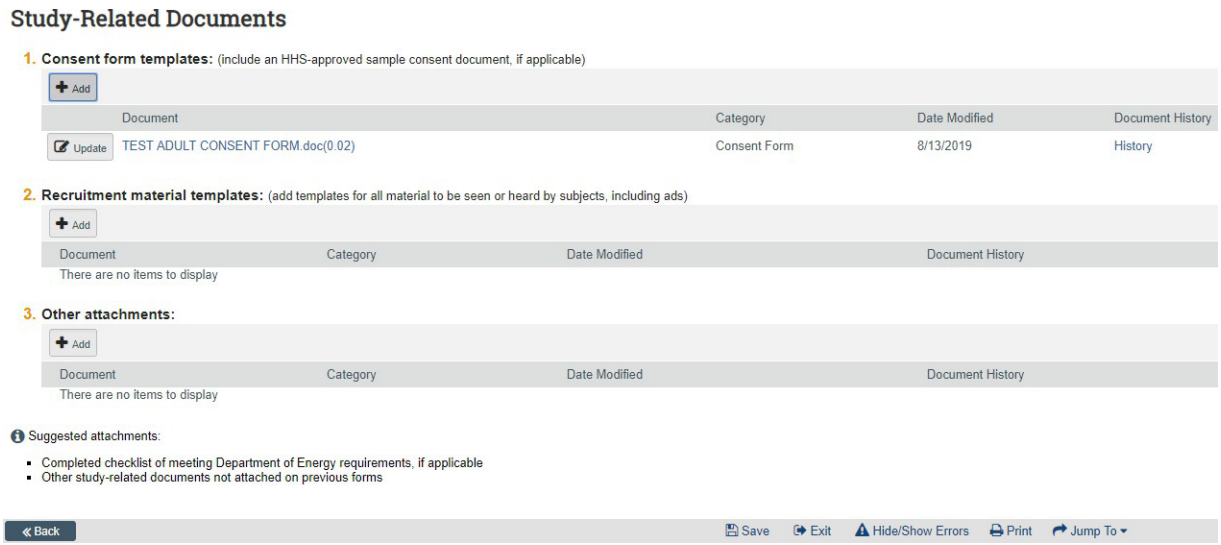


2. **Describe the update in the dialog box.** (If it is a personnel change, please list the full names of who is being added or removed from the study team here.)



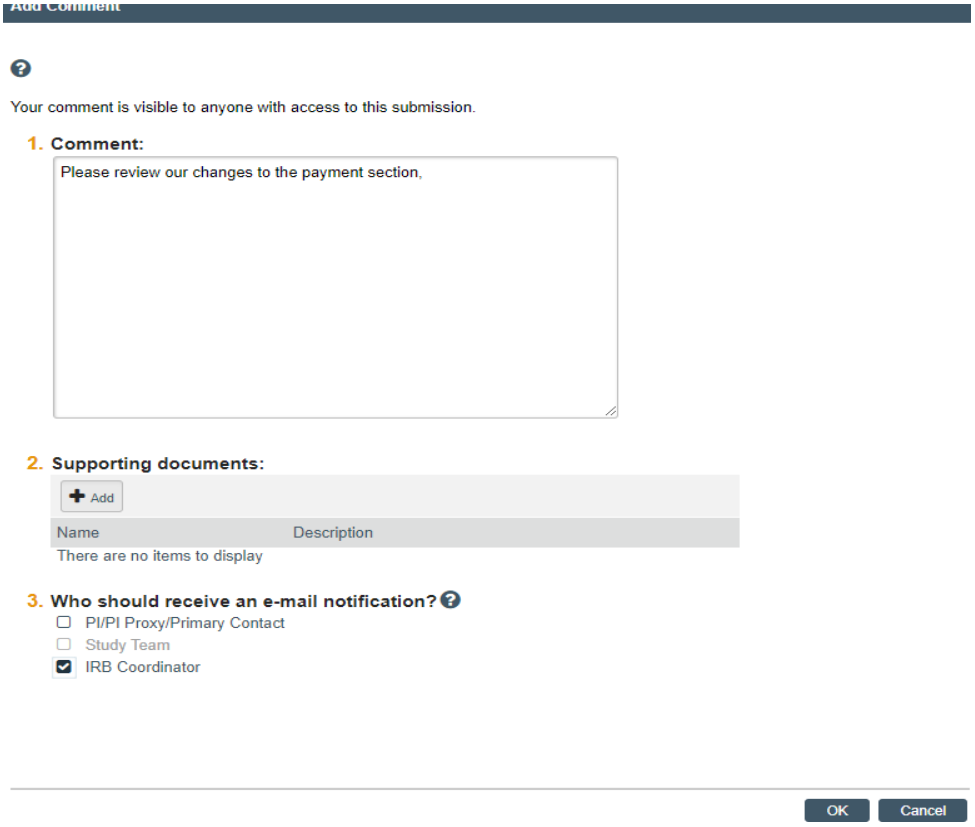
3. To update **External IRB Approval.**
    a. In the "Study Update Information" section please indicate that the study approval period is being updated.
    b. Then in the "External IRB" Section, please upload the current Approval Letter from the External IRB in question #3.

4. **For other Modifications, navigate to the Study-Related Documents if there are new/revised documents to submit.**
    a. Choose "Update" if you are replacing the document with a new version
    b. Choose "Add" if you have a new document to add to the study



5. **Navigate forward to finish the submission.** The status on Upper Left will say "Updating Study"

6. In the History Tab, add a Comment requesting the IRB's review of the changes. In item #3 choose to send an email notification to the IRB Coordinator, as shown below:



7. After IRB has accepts the change, you will get an email notification through the eCompliance system. The system does not allow a new letter to be sent, but acknowledgement will be shown in a public comment.