

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)	<ul style="list-style-type: none"> 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	<p>*Project Description for Full Committee Review, Exempt, Expedited, or Flex Review Studies</p> <ul style="list-style-type: none"> 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://kumcmmyIRB.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**.

The screenshot shows the myIRB Home Page. At the top is a blue header with the KU logo and 'STAGING' text. Below it is a red navigation bar with tabs: 'My Inbox', 'Home', 'IRB', 'COI', and 'Reports'. The 'My Inbox' tab is selected. On the left is a sidebar with sections: 'My Current IRB Actions' (with 'Create New Study' and 'Report New Information' buttons), 'My Current COI Activities' (with 'Create Update Certification' button), 'Shortcuts' (with 'COI Help' and 'IRB Help' links), and 'Web Page Links' (with 'Custom Search' and 'Management' links). The main content area is titled 'My Inbox' and contains a table of study items. The table has columns: ID, Name, SmartForm, Execute Activity, Date Created, State, and Coordinator. One item is listed: ID 'STUDY00141783', Name 'Study 1', SmartForm '[Edit]', Execute Activity '[Go]', Date Created '12/14/2017 10:47 AM', State 'Pre-Submission', and Coordinator. Below the table is a pagination bar showing '1 items' and 'page 1 of 1'. At the bottom of the page is a footer with 'eCompliance' and contact information for KU Lawrence and Edwards campuses, KU Medical Center, Kansas City, and KU School of Medicine, Wichita.

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.

The screenshot shows the 'Funding Sources' tab in the IRB submission system. At the top, there is a blue header with the KU logo and 'STAGING' text. Below the header, a navigation bar contains buttons for 'Back', 'Save', 'Exit', 'Hide/Show Errors', 'Print', 'Jump To', and 'Continue'. The main content area is titled 'Funding Sources' and includes a sub-header '1. Identify each organization supplying funding for the study:'. Below this is a table with columns for 'Funding Source', 'Sponsor's Funding ID', 'Grants Office ID', and 'Attachments'. A '+ Add' button is located above the table. The table is currently empty, with a message '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.

The screenshot shows the 'Study Team Members' tab in the IRB submission system. At the top, there is a blue header with the KU logo and 'STAGING' text. Below the header, a navigation bar contains buttons for 'Back', 'Save', 'Exit', 'Hide/Show Errors', 'Print', 'Jump To', and 'Continue'. The main content area is titled 'Study Team Members' and includes a sub-header '1. Identify each additional person involved in the design, conduct, or reporting of the research:'. Below this is a table with columns for 'Name', 'Roles', 'Financial Interest', 'Involved in Consent', 'E-mail', and 'Phone'. A '+ Add' button is located above the table. The table contains four rows of data, each with an 'Update' button to its left.

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

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](#)

This screenshot shows the navigation bar of the KU STAGING web application, identical to the one above, with 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.

This screenshot shows the top of the KU STAGING web application, including the blue 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: 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			

This screenshot shows the navigation bar of the KU STAGING web application, identical to the ones above, with 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
Update	acetaminophen	TYLENOL	
Update	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
Update	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: <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.

The screenshot shows the top of a web form titled "KU THE UNIVERSITY OF STAGING". Below the title is a navigation bar with buttons: "Back", "Save", "Exit", "Hide/Show Errors", "Print", "Jump To", and "Continue".

Local Site Documents ?

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

This section contains an "Add" button and a table with columns: Document, Category, Date Modified, and Document History. Below the table, it says "There are no items to display".

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

This section contains an "Add" button and a table with columns: Document, Category, Date Modified, and Document History. Below the table, it says "There are no items to display".

3. Other attachments:

This section contains an "Add" button and a table with columns: Document, Category, Date Modified, and Document History. Below the table, it says "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

The bottom navigation bar contains buttons: "Back", "Save", "Exit", "Hide/Show Errors", "Print", "Jump To", and "Continue".


INTERNAL REPORTING

Notes:

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

 THE UNIVERSITY OF
STAGING

Click Here to Submit Form - 3/10/2020 11:55AM

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.

 THE UNIVERSITY OF
STAGING

Click Here to Submit Form - 3/10/2020 11:55AM

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.

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.

The screenshot shows the main study page for STUDY00141856 in the KU Staging IRB system. The page is titled "STUDY00141856: Demo of a new study". The status is "Pre-Submission", indicated by a yellow bubble in the flowchart and a yellow status bar. A red banner at the top says "DRAFT SUBMISSION STAGE. Click 'Submit' or 'Notify PI' to send to IRB for review." The page includes a "Status Change Alert" section, a "Next Steps" section with buttons for "Edit Study", "Printer Version", and "View Differences", and a "History" section with tabs for "Funding", "Contacts", "Documents", "Reviews", and "Snapshots". The "History" section shows a table of activities, including "Study Created" by "Nelson, Nancy" on "12/27/2017 10:37 AM".

Pre-Submission

Last updated: 12/27/2017 11:20 AM

Status Change Alert

DRAFT SUBMISSION STAGE. Click "Submit" or "Notify PI" to send to IRB for review.

Next Steps

Edit Study

Printer Version

View Differences

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

Modifications Required

History

Funding

Contacts

Documents

Reviews

Snapshots

Filter: Activity

Enter text to search for

Go

Add Filter

Clear All

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

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.

The screenshot displays the KU STAGING IRB system interface. At the top, the header includes the KU logo, "THE UNIVERSITY OF STAGING", and a user greeting "Hello, Nancy Nelson". Below the header is a navigation bar with tabs: "My Inbox", "Home", "IRB", "COI", and "Submissions". The "Submissions" tab is active, showing a "Pre-Review" status for "STUDY00141856: Demo of a new study".

Status Change Alert: Success! Your submission has been sent to the IRB.

Next Steps: View Study, Printer Version, View Differences.

Study Details:

- Principal investigator: Nancy Nelson
- Submission type: Initial Study
- Primary contact: Nancy Nelson
- PI proxies:
- IRB office: KUMC
- IRB coordinator:

Flowchart: Pre-Submission → Pre-Review (highlighted) → IRB Review → Post-Review → Review Complete. Clarification Requested and Modifications Required are shown as feedback loops.

History Table:

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.

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.

1

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.

View Differences

Create Modification/CR

Report New Information

Modification / Continuing Review / Study Closure

*** What is the purpose of this submission? ?**

☒ Continuing Review

☐ Modification

☐ Modification and Continuing Review

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**.

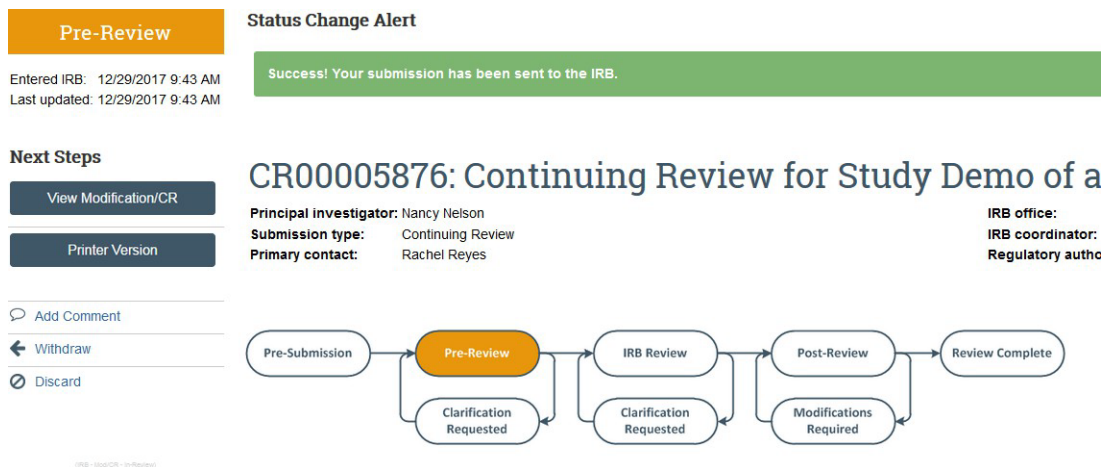
2. Research milestones: (select all that apply) ?

- ☒ Study is permanently closed to enrollment OR was never open for enrollment
- ☒ All subjects have completed all study-related interventions OR not applicable (e.g. study did not include interventions, no subjects were enrolled)
- ☒ Collection of private identifiable information is complete OR not applicable (no subjects were enrolled)
- ☒ Analysis of private identifiable information is complete OR not applicable (no subjects were enrolled)
- ☐ Remaining study activities are limited to data analysis
- ☐ Study remains active only for long-term follow-up of subjects

i Important! If the first four research milestones above are complete, the study will be closed to discontinue IRB oversight.

*** I acknowledge that this study will be closed:** ☒

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.




Home IRB COI

IRB > IRB Submissions > staging test > Modification #8 for Study STUDY00000003

Pre-Submission

Entered IRB:
Approval:
Effective:
Modified: 7/24/2013 3:32 PM

Investigator: Anita Anderson
Submission type: Modification
Primary contact: [Nathan Ness](#)
IRB coordinator:



My Current Actions

Edit Modification / CR
Printer Version
View Differences

Submit
 Discard
 Add Comment
 Manage Ancillary Reviews

History Project Contacts Documents

Filter by Activity [Advanced](#)

Activity	Author	<input checked="" type="checkbox"/> Activity Date
PI Notified	Ness, Nathan	7/24/2013 3:32 PM CDT

2

University of Kansas Medical Center – Human Research Protection Program

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.

The screenshot shows the University of Kansas logo at the top. Below it, the date and time are displayed as "Date: Wednesday, July 24, 2013 4:19:12 PM" and "View: SF: Modification/CR". There are "Print" and "Close" buttons in the top right corner. The main heading is "Modification / Continuing Review". Below this, a section titled "* What is the purpose of this submission?" contains three radio button options: "Continuing Review", "Modification" (which is selected), and "Modification and Continuing Review". A "Modification Scope:" section lists "Study team member information" and "Other parts of the study". Below this is a table with two columns: "Active modification for this study" and "Modification type(s)". The table content shows "View: SF: Modification Information". The main heading for the table is "Modification Information". Below this, there are three numbered sections: 1. "Study enrollment status:" with the text "Subjects are currently enrolled"; 2. "Notification of subjects: (check all that apply)" with the text "There are no items to display"; and 3. "* Summarize the modifications:" with a list of two items: "1. Adding statistician to the study team" and "2. Submitting revised investigator's brochure". An "Attach files:" section is also present, with the text "If notifying subjects, add a description of how they will be notified to the Supporting Documents page."

THE UNIVERSITY OF KANSAS

Date: Wednesday, July 24, 2013 4:19:12 PM Print Close

View: SF: Modification/CR

Modification / Continuing Review

*** What is the purpose of this submission?**

☐ Continuing Review

☒ **Modification**

☐ Modification and Continuing Review

Modification Scope:

Study team member information

Other parts of the study

Active modification for this study	Modification type(s)
View: SF: Modification Information	

Modification Information

- 1. Study enrollment status:**
Subjects are currently enrolled
- 2. Notification of subjects: (check all that apply)**
There are no items to display
- 3. * Summarize the modifications:**
 1. Adding statistician to the study team
 2. Submitting revised investigator's brochure

Attach files: If notifying subjects, add a description of how they will be notified to the Supporting Documents page.

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.

View Changes to IRB Submission: [IRB00001366](#)

Show Changes made between Current Version (9.0) and 8.0 7/24/2013 3:22 PM Study Approved

Changed Steps: Study Team Members << >> ☒ Limit Steps to Current SmartForm Path

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
Byron Branson	Data Analyst	no	no	hscl@ku.edu
Chris Cross	Pharmacist	no	no	hscl@ku.edu
David Delorio	Statistician	no	no	hscl@ku.edu
Francis Firth	Research Personnel	no	no	hscl@ku.edu
Tyann Orton	Lay Observer	no	no	torton@kumc.edu

Differences

Added: David Delorio

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.

View Changes to IRB Submission: [IRB00001366](#)

Show Changes made between Current Version (9.0) and 8.0 7/24/2013 3:22 PM Study Approved

Changed Steps: Drugs << >> ☒ Limit Steps to Current SmartForm Path

Drugs

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

Generic Name	Brand Name	Attachment Name
MTXA443		Investigator's brochure 5-13-13

Differences

Added: MTXA443

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.

The screenshot displays the University of Kansas IRB submission system interface. At the top is the KU logo and navigation links: Home, IRB, and COI. Below this is a breadcrumb trail: IRB > IRB Submissions > staging test > Modification #8 for Study STUDY00000003.

The main header area shows the title **MOD000000027: Modification #8 for Study STUDY00000003**. To the left, under the 'Pre-Submission' tab, are fields for: Entered IRB, Approval, Effective date (7/24/2013 3:32 PM), and Modified. To the right, it lists: Investigator (Anita Anderson), Submission type (Modification), Primary contact (Nathan Ness), and IRB coordinator. Further right, it specifies IRB: KUMC and Letter: None.

A workflow diagram illustrates the process: Pre-Submission leads to IRB Pre-Review, which can lead to IRB Review or Clarifications Requested. IRB Review can lead to Post Review or Clarifications Requested. Post Review can lead to Review Complete or Modifications Required. Clarifications Requested can lead back to the preceding step.

On the left, 'My Current Actions' includes buttons for Edit Modification / CR, Printer Version, View Differences, Submit, Discard, Add Comment, and Manage Ancillary Reviews.

The 'History' tab is active, showing a table of activities. The table has columns for Activity, Author, and Activity Date. A filter bar at the top of the table allows filtering by Activity (set to 'PI Notified'), with 'Go', 'Clear', and 'Advanced' options.

Activity	Author	Activity Date
PI Notified	Ness, Nathan	7/24/2013 3:32 PM CDT

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:

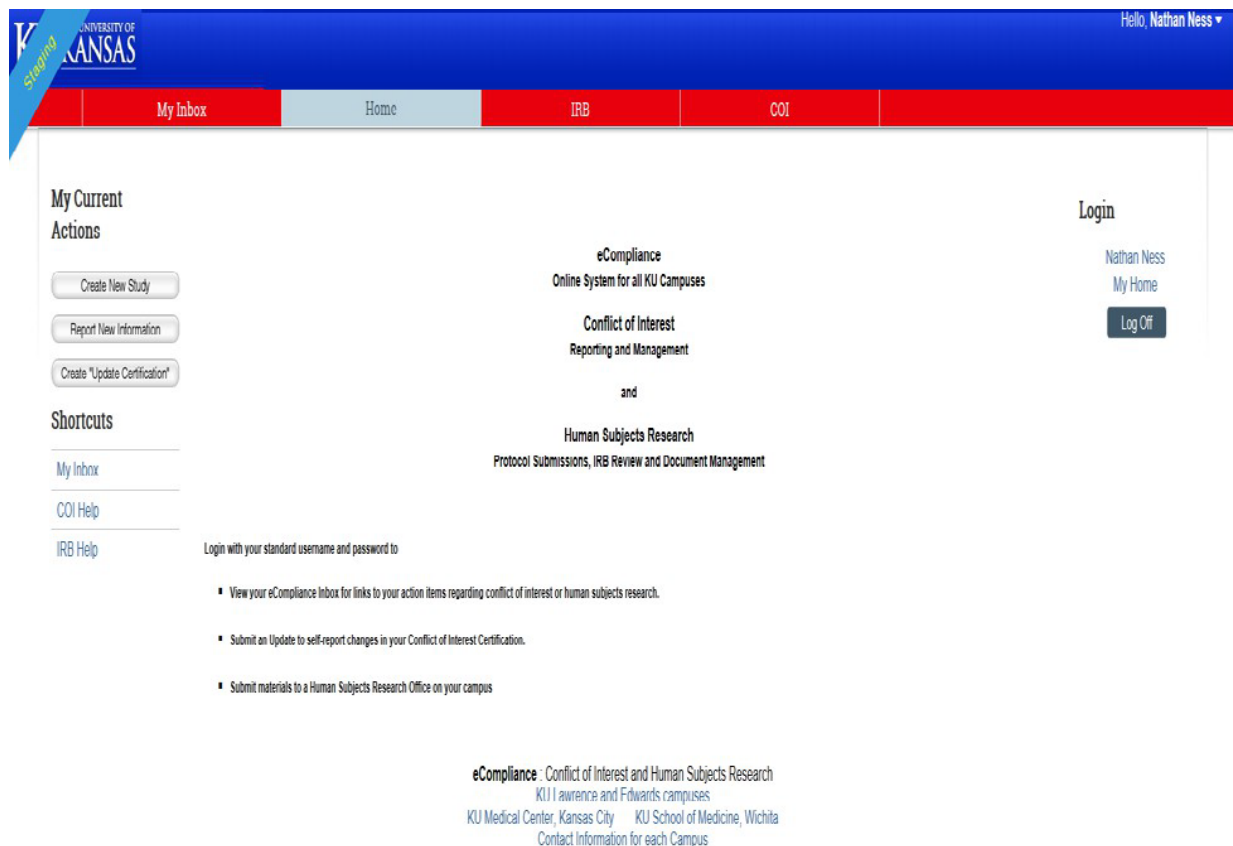
<https://kumcmmyIRB.huronresearchsuite.com>.

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**. (This 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”.

External IRB

1. * External IRB: ?

Western Institutional Review Board ...

2. External study ID: ?

3. Specify the reason the study should be reviewed by an external IRB:

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:

<div>+ Add</div>			
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: ?

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

« Back

Save

Exit

Hide/Show Errors

Print

Jump To ▾

Continue »

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.

Study Scope ?

1. * 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](#)

2. * Does the study evaluate the safety or effectiveness of a device or use a humanitarian use device (HUD)?

☐ Yes ☒ No [Clear](#)

« Back

Save

Exit

Hide/Show Errors

Print

Jump To ▼

Continue »

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.

Local Research Locations ?

1. Identify research locations where research activities will be conducted or overseen by the local investigator:

+ Add

Location	Contact	Phone	Email
----------	---------	-------	-------

There are no items to display

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Hide/Show Errors

Print

Jump To ▼

Continue »

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.

Drugs

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

				
	Generic Name	Brand Name	Manufacturer Name	Attachment Name
	acetaminophen	TYLENOL		Investigator's Brochure.docx

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

☒ Yes ☐ No [Clear](#)

3. * Identify each IND:

			
	IND Number	IND Holder	Other Holder
	12345	Sponsor	

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

				
	Document	Category	Date Modified	Document History
	FDA IND letter.docx(0.01)	Drug Attachment	8/8/2019	History

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.

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
There are no items to display		

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

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.

Final Page 0

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 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.

Pre-Submission

Last updated: 8/9/2019 10:25 AM

Status Change Alert

DRAFT SUBMISSION STAGE. Click "Submit" or "Notify PI" to send to IRB for review.

Next Steps

Edit Study

Printer Version

View Differences

Submit

Assign Primary Contact

Manage Ancillary Reviews

Manage Guest List

Correspond with sIRB

Add Comment

Copy Submission

Discard

NotifyPI

Verify SFI

Verify Training

STUDY00144101: This is Test Study 3

Principal investigator: Nathan Ness

Submission type: Initial Study

Primary contact: Nathan Ness

PI proxies: [Ribbon Display Options](#)

IRB office: KUMC

IRB coordinator:

External study ID: Test Study 03

```

graph LR
    A([Pre-Submission]) --> B([Pre-Review])
    B --> C([Pending sIRB Review])
    C --> D([Post-Review])
    D --> E([Review Complete])
    B --> F([Clarification Requested])
    F --> C
    D --> G([Modifications Required])
    G --> C
  
```

History Funding Contacts Documents Reviews Snapshots

Filter by

Activity

Enter text to search for

Q

+ Add Filter

x Clear All

Activity	Author	Activity Date
Study Created	Ness, Nathan	8/8/2019 2:15 PM

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.

Pre-Review

Entered IRB: 8/9/2019 10:36 AM
Last updated: 8/9/2019 10:36 AM

Next Steps

View Study

Printer Version

View Differences

Assign Primary Contact

Manage Ancillary Reviews

Manage Guest List

Correspond with sIRB

Add Comment

Copy Submission

Withdraw

Discard

Verify SFI

Venty Training

Status Change Alert

STUDY00144101: This is Test Study 3

Principal investigator: Nathan Ness
Submission type: Initial Study
Primary contact: Nathan Ness
PI proxies:

IRB office: KUMC
IRB coordinator:
External study ID: Test Study 03

```

graph LR
    A[Pre-Submission] --> B[Pre-Review]
    B --> C[Pending sIRB Review]
    C --> D[Post-Review]
    D --> E[Review Complete]
    C -- Clarification Requested --> B
    D -- Modifications Required --> C

```

History

Funding

Contacts

Documents

Reviews

Snapshots

Filter by: Activity

Enter text to search for

Q

+ Add Filter

✕ Clear All

Activity	Author	Activity Date
Submitted	Ness, Nathan	8/9/2019 10:36 AM
Study Created	Ness, Nathan	8/8/2019 2:15 PM

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

Active

Entered IRB: 7/25/2019 4:02 PM
Initial approval: 7/25/2019
Initial effective: 7/25/2019
Effective: 7/25/2019
Approval end: 7/24/2020
Last updated: 7/26/2019 8:20 AM

Principal Investigator: Nathan Ness
Submission type: IRB Site
Primary contact: Nathan Ness
PI proxies:
Institution: Children's Mercy Hospitals & Clinics

IRB office: KUMC
IRB coordinator:
Letter: Correspondence_for_STUDY00144096.pdf(0.01)
Regulatory authority: Pre-2018 Requirements
External study ID:

Next Steps

- View Site
- Printer Version
- View Differences
- Create Site Modification
- Update Study Details**
- Report New Information
- Assign Primary Contact
- Manage Ancillary Reviews
- Manage Guest List
- Report Continuing Review Data

Workflow Diagram:

```
graph LR; A[Pre-Submission] --> B[Pre-Review]; B --> C[Pending sIRB Review]; C --> D[Post-Review]; D --> E[Review Complete]; C --> F[Modifications Required]; F --> B;
```

History

Activity	Author	Activity Date
Letter Sent	Ivanovich, Irina	7/26/2019 8:20 AM
Correspondence_for_STUDY00144096.pdf	Ivanovich, Irina	7/26/2019 8:19 AM
Finalized Documents	Ivanovich, Irina	7/25/2019 4:32 PM
Reliance Confirmed	Ness, Nathan	7/25/2019 4:02 PM
Submitted	Ness, Nathan	7/25/2019 4:00 PM
Study Created		

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.)

Study Update Information

1. ★ Summarize the updates: ?

The sponsor has decided to offer payment for participation. |

« Back

Save

Print

3. To update **External IRB Approval**.

- In the “Study Update Information” section please indicate that the study approval period is being updated.
- 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.

- Choose “Update” if you are replacing the document with a new version
- Choose “Add” if you have a new document to add to the study

Study-Related Documents

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

+ Add

Document	Category	Date Modified	Document History
 Update TEST ADULT CONSENT FORM.doc(0.02)	Consent Form	8/13/2019	History

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

+ Add

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

3. Other attachments:

+ Add

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 study-related documents not attached on previous forms

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Save

Exit

Hide/Show Errors

Print

Jump To ▾

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:



Your comment is visible to anyone with access to this submission.

1. Comment:

Please review our changes to the payment section.

2. Supporting documents:

+ Add

Name	Description
------	-------------

There are no items to display

3. Who should receive an e-mail notification? ?

- ☐ PI/PI Proxy/Primary Contact
- ☐ Study Team
- ☒ IRB Coordinator

OK

Cancel

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.