INVESTIGATOR GUIDANCE
Submitting a ‘Request for External IRB’ Study in eIRB

The eCompliance software allows you to prepare your study documents in advance and then upload them for electronic review.

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

Logging in takes you to your personalized Home Page
On the left, you will notice a button to Create New Study (below is a picture from a test account)

Once you select “Create New Study” you will be directed to the first tab “Basic Information.”
**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.
- For item #7, select Yes
- For item #8, select Single-site study
- For item #9, choose “Add” to upload the Protocol.

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**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 manage 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.)*
   - Single-site study (One institution conducting study activities)
   - Multi-site study (Multiple institutions conducting study activities)
   - Clear

9. Attach the protocol:
   - Document  Category  Date Modified  Document History
   - There are no items to display
EXTERNAL IRB

Notes:

- For item #1, select the External IRB from the list. If the External IRB is not listed, please contact the IRB office.
- For items #3 through #5, upload the approval letter and include the approval dates of the original study approved by the External IRB (i.e. before KUMC is added as a site)
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 SCOPE

Notes:
- This page has branching logic on both questions. If your study involves drugs or devices, you will complete this page and then provide details in subsequent pages. Please refer to the ‘Submitting a New Study in eCompliance’ guide if you need assistance with these subsequent pages.
FINAL PAGE

Notes:
- Click ‘Finish’ to complete entering information about the EXTERNAL IRB. This will return you to the STUDY page.

STUDY PAGE

Notes:
- Here, you will navigate to the SITE page to upload further documentation specific to KUMC. Click on either one of the two SITE links to access the SITE page.
SITE PAGE

Notes:
- Once on the SITE page, click ‘Edit Site’ to get to the first STUDY tab “Basic Information.”

BASIC INFORMATION

Notes:
- Some fields will be pre-populated
- For item #3, briefly summarize the study.
- For item #4, list the KUMC Principal investigator
- For item #5, indicated whether the KUMC Principal investigator has a financial interest related to the research.
- For item #6, select the KUMC IRB.
FUNDING SOURCES

Notes:

- Enter any SITE specific funding. If there is only one funding source, and you have already entered this on the EXTERNAL IRB tab, you do not need to repeat this step.
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 members are also listed.
- Contact the IRB office if you do not find an individual’s name; we will instruct you on how to have them added.

RESEARCH LOCATIONS
Notes:
- Add each external research location and their contact.
- Contact the IRB office if you have questions about this section.
LOCAL SITE DOCUMENTS

Consent forms:

Notes:
- Upload:
  - The **External IRB approved consent form(s)** AND
  - The **proposed KUMC consent form draft(s)**
    - Created by customizing the External IRB approved consent form. Contact the IRB office if you require assistance.

Recruitment materials:

Notes:
- Add **Recruitment materials** that will be used by the KUMC investigators.

Other attachments:

Notes:
- Use this section to upload all other documents required for KUMC local context review.
- Every submission must be accompanied by 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, KCUMB)
- Upload an **Administrative Certification** from your Department Chair.
  - Administrative Certifications for those in Internal Medicine can be electronically routed.
  - If the PI is the department chair, no administrative certification is required.
- Upload PRMC approval (for cancer studies only)
- Upload any **Submissions to Ancillary Review committees** (e.g. Radiation, Nursing Impact)
- Please classify your documents by applicable category
**FINAL PAGE**
Click Finish to save and exit the form.

**MAIN STUDY PAGE**
Now your SITE is created. Notice that the SITE 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 SITE is in Pre-submission, the SITE can be edited by the PI or study team. The SITE stays in Pre-submission until the PI hits the “Submit” button. Any member of the study team can create a Study/SITE, but only the principal investigator has the “Submit” button. Other team members will see a button that says “Notify PI.”
SUBMIT THE SITE
Notice that once the SITE is submitted, the orange flow chart bubble moves to the IRB Pre-Review status. Note also that the submission has been locked and the “Edit Site” button has been replaced with “View Site.” A green banner will flash across the top of the screen as indicated below to confirm successful submission of the SITE. If desired, the PI can add a comment with the submission. The comment is viewable by anyone who has access to the Study/SITE.

IRB PRE-REVIEW, REVIEW OR POST REVIEW
While the SITE remains viewable, it cannot be edited while its status displays one of these categories. The IRB staff members are reviewing it and may request clarifications from you.

SUBMISSION TO EXTERNAL IRB
Once KUMC IRB staff members have finished their local context review of the study materials and all ancillary reviews are completed, you will be instructed to submit the KUMC documents to the External IRB. **Please coordinate this process with the lead study team at the External IRB.** For reliance on commercial IRBs, follow the steps required for study submission by those IRBs.

Once you have received IRB approval for KUMC, please access the SITE page, click **Edit Site**, and upload the KUMC documents approved by the External IRB. Include the approval letter adding KUMC as a site under: **Other attachments.** Click **Submit Responses** on the SITE page to send the Study/Site back for final acknowledgment.

IRB staff will generate a letter confirming that IRB approval is in place.