INVESTIGATOR GUIDANCE
Submitting a New Study in eIRB

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

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

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

Once you select “Create New Study” you will be directed to the first of 7 required tabs. As you complete the questions, you may also be prompted to answer questions on 3 additional tabs, if relevant to your study.

BASIC INFORMATION
Notes:
- The ‘Short Title’ is how the study is referenced throughout the system.
- Select the KUMC IRB. Consult the IRB office for further instructions if the study will be conducted on the Lawrence campus.
- On item #8, 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 autopopulated 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 sites, drugs or devices, you will complete this page and then provide details in subsequent pages.

External Sites (if applicable)

- Add each external site and their contact. Indicate whether the external IRB will review or the external site will rely on the KUMC IRB review.
- 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.

(topic continued on next page)
Institutional Review Board (IRB) Application

Drugs

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

   - Generic Name
   - Brand Name
   - Attachment Name

2. Will the study be conducted under any IND numbers? Yes No

   - IND Number
   - IND Holder
   - Other Holder
   - Sponsor

3. Add files (such as IND or other information that was not attached for a specific drug):
   - Document
   - Category
   - Date Modified

Devices

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

   - Device Name
   - Humanitarian Use Device
   - Attachment Name

2. Device exemptions applicable to this study:
   - IDE number
   - HDE number
   - Claim of abbreviated IDE (non-surgical RMI device)
   - Exempt from IDE requirements

3. If applicable, identify each IDE and HDE number:

   - IDE / HDE Number
   - IDE / HDE Holder
   - Other Holder

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

   - Document
   - Category
   - Date Modified

Investigational drugs are typed in by hand.
Upload the investigator’s brochure if applicable
Indicate the IND and IND Holder if applicable.

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
CONSENT FORMS AND RECRUITMENT MATERIALS

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

INTERNAL REPORTING

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

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

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 blue bubble and the yellow bar indicate “Pre-submission.”

As long as the study is in Pre-submission, the study can be edited by the PI or study team. The study stays in Pre-submission until the PI hits the “Submit” button. Any member of the study team can create a study, but only the principal investigator has the “Submit” button. Other team members will see a button that says “Notify PI.”
SUBMIT THE STUDY
Notice that once the study is submitted, the blue bubble moves to the IRB 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.

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