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. 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://ecompliance.ku.edu.

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:
   - Document: TEST_PROTOCOL.doc(0.01)
     - Category: IRB Protocol
     - Date Modified: 8/8/2019
     - Document History
   Add

March 2020
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”.

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**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 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 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.

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**Drugs**

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

<table>
<thead>
<tr>
<th>Generic Name</th>
<th>Brand Name</th>
<th>Manufacturer Name</th>
<th>Attachment Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>acetaminophen</td>
<td>TYLEMOL</td>
<td></td>
<td>Investigator's Brochure.docx</td>
</tr>
</tbody>
</table>

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

   - Yes
   - No
   - Clear

3. *Identify each IND:*

<table>
<thead>
<tr>
<th>IND Number</th>
<th>IND Holder</th>
<th>Other Holder</th>
</tr>
</thead>
<tbody>
<tr>
<td>12345</td>
<td>Sponsor</td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Document</th>
<th>Category</th>
<th>Date Modified</th>
<th>Document History</th>
</tr>
</thead>
<tbody>
<tr>
<td>FDA.IND letter.docx(0.01)</td>
<td>Drug Attachment</td>
<td>8/5/2019</td>
<td>History</td>
</tr>
</tbody>
</table>
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 http://www.kumc.edu/human-research-protection-program/institutional-review-board/irb-reliance-resources/reliance-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)

<table>
<thead>
<tr>
<th>Document</th>
<th>Category</th>
<th>Date Modified</th>
<th>Document History</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adult Consent Formacked0.01</td>
<td>Consent Form</td>
<td>8/9/2019</td>
<td>History</td>
</tr>
<tr>
<td>IRB-Approved Global Consent Template.docx(0.01)</td>
<td>Consent Form</td>
<td>8/8/2019</td>
<td>History</td>
</tr>
</tbody>
</table>

#### 2. Recruitment materials: (Add all material to be seen or heard by subjects, including audio)

<table>
<thead>
<tr>
<th>Document</th>
<th>Category</th>
<th>Date Modified</th>
<th>Document History</th>
</tr>
</thead>
<tbody>
<tr>
<td>TEST ADVERTISEMENT.doc(0.01)</td>
<td>Recruitment Materials</td>
<td>8/8/2019</td>
<td>History</td>
</tr>
</tbody>
</table>

#### 3. Other attachments:

<table>
<thead>
<tr>
<th>Document</th>
<th>Category</th>
<th>Date Modified</th>
<th>Document History</th>
</tr>
</thead>
<tbody>
<tr>
<td>TEST DATA COLLECTION SHEET.doc(0.01)</td>
<td>Data Collection Sheet</td>
<td>8/8/2019</td>
<td>History</td>
</tr>
<tr>
<td>Tool Project description document.doc(0.01)</td>
<td>Supplemental Application Form</td>
<td>8/8/2019</td>
<td>History</td>
</tr>
<tr>
<td>Nasc SCIENTIFIC REVIEWER CHECKLIST.doc(0.01)</td>
<td>Scientific Reviewer</td>
<td>8/8/2019</td>
<td>History</td>
</tr>
</tbody>
</table>

### Suggested attachments:
- Completed checklist of meeting Department of Energy requirements, if applicable
- Other site-related documents not attached on previous forms
1. * Categorize your study as one of the following:

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
</tr>
</thead>
</table>

- **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.
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, will only be able to see a button that indicates to “Notify PI”. The PI must be notified to “Submit” the study.
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 eIRB 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.