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 eIRB 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:

<table>
<thead>
<tr>
<th>RE:</th>
<th>Notification to the PI</th>
</tr>
</thead>
<tbody>
<tr>
<td>IRB Study ID#:</td>
<td>MOD000027</td>
</tr>
<tr>
<td>Study Title:</td>
<td>Modification #1 for Study 155555</td>
</tr>
<tr>
<td>Type of Submission:</td>
<td>Modification</td>
</tr>
</tbody>
</table>

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 eIRB. Log in with your standard KUMC user name and password. You will see the modification screen with details about your study, shown in the following example. Notice that the modification is in a state of “Pre-Submission” because it has not been sent to the IRB.
STEP 2: REVIEW THE PROPOSED CHANGES

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

![Modification Screen](image)

Modification Information

1. Study enrollment status:
   Subjects are currently enrolled

2. Notification of subjects: (check all that apply)
   There are no items to display

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

3. * Summarize the modifications:*
   1. Adding statistician to the study team
   2. Submitting revised investigator’s brochure

Hit “Close” to go back to the modification screen.

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

![New Study Team Member](image)
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

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

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

Once you click through all the Changed Steps, you **CLOSE** the view and return to the main page.
STEP 3: SUBMIT THE MODIFICATION TO THE IRB

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