The SLU eIRB tip of the month

As a protocol undergoes review, the IRB may ask that comments be addressed (these are also known as contingencies) in order to modify the protocol and work toward approval. This process can be completed by the Principal Investigator and/or any Administrative Contact listed on the protocol. In this month’s tip, we'll demonstrate how to respond to the IRB's comments within the eIRB system. Please see the attached tip.

For further tips or instruction, please see the eIRB user guides and quick sheets on the IRB web site. Previous tips may also be accessed here.

The IRB Office

(314) 977-7744
As your protocol undergoes review, the IRB may ask you to address comments (also known as contingencies) in order to modify your protocol and to work toward approval. This process can be completed by the Principal Investigator (PI) and/or any Administrative Contact listed on the protocol. In this month’s tip, we’ll demonstrate how to respond to the IRB’s comments within the eIRB system.

1. The PI and any Administrative Contact listed on the protocol will receive an email when comments have been issued from the IRB office. Unlike a basic notification email, the comments email indicates that action is needed on the part of the research team (i.e., ***Action Necessary*** appears in the email body). Instructions on addressing the comments are also contained in the body of the email. See Example 1 below.

Example 1:

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IRB Comments sent (Cycle 1): 20246, Millinger, Rachel

***Action Necessary***

The IRB has reviewed the following protocol and has requested clarification or additional information.

Protocol ID: 20246
Principal Investigator: Millinger, Rachel
Department: Office of Research Integrity
Protocol Title: TEST RIS Exempt TEST
Form Type: AMENDMENT

Please go to https://eirb.slue.edu and click on the protocol event status to access the IRB comments, provide responses and to make any revisions to your protocol.

If this is a new protocol, the IRB requests a response within 60 days. Thereafter, the protocol may be administratively closed. A response should be more immediate for any other form/submission type, particularly continuing reviews.

Your response will be returned to IRB reviewers. After that review, you will be informed whether the submission received approval.

If you have any questions, please contact the IRB office at 314-977-7744.

For new studies, please note that the study should not be commenced or potential subjects approached or enrolled into this study until you have received a full approval letter from the IRB.
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2. The ‘Protocol Event’ status on the dashboard will change to say “Comments Received (Cycle 1)”. To begin addressing the comments, click on that link to navigate to the comments page. See Example 2 below. From the comments page you can access the protocol to make changes, read the specific items the IRB would like you to address, and respond to the comments. Your responses will be sent from the comments page and not from within the protocol. See Example 3 below. Click the ‘Show All Comments’ button to view your comments in table form. This will allow you to clearly see which comments still require a response. See Example 4 below.

Example 2:
Example 3:

The IRB has requested action on the following items. Provide a response to each required item (responses to suggested items are optional) and save. Click on ‘Get Protocol’ to make necessary edits to the protocol based on the comments below. If revisions are requested to any attachments (consent documents, recruitment materials, etc), please delete the old version and upload the new version with changes highlighted in yellow. If the attachment is in a file format other than Microsoft Word, also attach a clean copy (highlights removed) for the IRB to stamp.

Protocol ID: 24317 (IRB3, Guest3)
Cycle: 

Comments

The section of the protocol the comment is in regards to

The specific comment from the IRB

Type your response here. It may simply indicate that you have addressed the comment in the protocol or made changes within the form. Your response may also be a bit longer to communicate with the IRB.

Example 4:

The IRB has requested action on the following items. Provide a response to each required item (responses to suggested items are optional) and save. Click on ‘Get Protocol’ to make necessary edits to the protocol based on the comments below. If revisions are requested to any attachments (consent documents, recruitment materials, etc), please delete the old version and upload the new version with changes highlighted in yellow. If the attachment is in a file format other than Microsoft Word, also attach a clean copy (highlights removed) for the IRB to stamp.

Protocol ID: 24317 (IRB3, Guest3)
3. When all of the comments have been addressed, click the ‘Submit to IRB’ button to submit your responses back to the IRB. All comments must be addressed and changes should be made within the protocol. The eIRB system will not let the responses be submitted until all comments have been addressed. An error message will remind you to complete all responses. See Example 5 below. The eIRB system will issue one pop-up reminder to make changes in the protocol, but won’t stop responses from being submitted even if changes are not made. Don’t submit a protocol without making your changes! See Example 6 below.

Example 5:

![Example 5 Image]

Example 6:

![Example 6 Image]

4. If, after trying to submit, you receive the error, “Please fill protocol from completely.” You will need to open the protocol in Edit mode and run the Check For Completeness. This feature will tell you what still needs to be completed within the protocol before you can submit the responses. The open protocol pop-up should be presented automatically with the error message. See Example 7 below.

Example 7:

![Example 7 Image]
5. To communicate items to the IRB which are unrelated to the comments you are addressing, use the “Additional Responses to IRB” box at the bottom of the comments page.

![Additional Responses to IRB](image)

6. Protocols with multiple comment cycles maintain the previous round of comments for your reference. To access previous comments use the cycle icon located on the comments page. See Example 8 below. For multiple cycles, the Show All Comments page will display the current cycle and any previous cycles. See Example 9 below.

**Example 8:**

The IRB has requested action on the follow optional) and save. Click on “Get Protocol” to
if revisions are requested to any attachment
the new version with changes highlighted in
copy (highlights removed) for the IRB to stam

![Example 8](image)

**Example 9:**

![Example 9](image)

* This tip was prepared in June 2014. Please note that information given in this tip and/or the screen shots used could change or become outdated in the future. Rely on the IRB website for the most current and up-to-date information regarding IRB policies and procedures or call the IRB office at (314) 977-7744 with any questions.*