The SLU eIRB tip of the month

In this month’s tip we will demonstrate how to change the Principal Investigator (PI) of an existing protocol in eIRB. The process to change the PI differs depending upon whether the former PI has a designated Administrative Contact on his/her protocol and upon what state the protocol is in. 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

December2015_eIRBTip_ResearchCommunity_ChangingThePI.pdf
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In this month’s tip we will demonstrate how to change the Principal Investigator (PI) of an existing protocol in eIRB. The new PI will need to complete several requirements in order to assume responsibility of an existing protocol. The process to change the PI differs depending upon whether the former PI has a designated Administrative Contact on his/her protocol and upon what state the protocol is in.

A request to change the PI should be made immediately on either an Amendment form created for this purpose or on the Continuing Review form at the time of renewal. The new PI and the former PI cannot facilitate this change alone. A third person must facilitate the change.

The following must be in place before changing the PI:

- If an Administrative Contact is listed on the protocol, he/she will create the appropriate form and switch the PI, as the former PI, once replaced in the Personnel Information section, will be unable to access the protocol.
- If no Administrative Contact is listed, the former PI must add a third person in the Admin Contact role to facilitate the change before any other action can be taken.
- If the former PI is no longer affiliated with SLU, click here for more information. The IRB Office will need to facilitate the change in this case.

Follow the steps below to change the PI:

1) On the Amendment (shown below) or Continuing Review form, detail the proposed personnel changes (along with any other changes) and provide justification/explanation as indicated.

Any submission to change the PI must also include a signed Department Chair Approval Form. This form is to be completed with the new PI’s name, the Department Chair’s signature, and uploaded to the Attachments section of the protocol. It is not possible to complete the Department Chair review in the system like you did when the protocol was first submitted. Note: failure to include this review could result in a returned submission.

Note: If the protocol is new, in preparation or not yet approved, skip to Step 2. The Department Chair review may still need to be redone depending on the status at the time of the change. Note that the protocol cannot be edited during while the pre-review process is underway or when you have sent responses to IRB comments.
2) In the Personnel Information section replace the entry of the former PI by clicking the binoculars icon and using the ‘Find User’ feature to search for the new PI. The new PI’s information will auto-populate into the protocol, but will need to be updated as appropriate.

Note: When using the search feature, less entered information will yield more results.

3) After the new PI has been selected, his/her human subjects training information will auto-populate into the protocol at the end of the PI record. If training information does not auto-populate, proof of training will need to be attached in the Attachments section. Note: failure to include proof of training could result in a returned submission.

4) The new PI’s ‘Research Experience’ and ‘Research Duties’ will need to be manually entered, as this information will not auto-populate and may retain the former PI’s entry.
5) If the former PI is to remain on the research team, he/she may be added under another role on the Personnel Information page, such as Non-SLU Collaborator. Only one person may fill any one role in the Personnel Information section and only the PI or Administrative Contact(s) may edit.

**Note:** All Non-SLU Collaborators will need to have proof of human subjects research training uploaded to the Attachments section of the protocol as the training is not linked within the system.

6) Once the change is complete, the new PI will have access to the protocol and will be prompted to complete the PI Obligations section and to readdress all questions on the page. It is recommended to run the ‘Check for Completeness’, found in the left menu of blue bars, to ensure that all elements of the protocol are completed before clicking ‘Submit’.

7) Be sure to remove the former PI’s name and contact information from all study materials, and replace with the new PI’s name and contact information. This includes but is not limited to: patient materials such as informed consent and HIPAA Authorization documents, flyers, brochures; as well as inter-office documents such as fund requests. Upload these updated materials reflecting the new PI to the appropriate sections of the protocol when submitting to change the PI.

8) If the former PI is no longer affiliated with SLU (i.e., has graduated from or is no longer employed by the University), no Administrative Contact has been designated for the protocol, and the study is to continue, the PI change will need to be facilitated with help from the IRB Office. Please contact the IRB Office at irb@slu.edu or 977-7744 (or your IRB Coordinator) to begin the process.
If you have any questions about the content of this tip, or need assistance in the eIRB submission process, call the IRB Office at 977-7744 or email irb@slu.edu.

This tip was prepared in December 2015. 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.