The SLU eIRB tip of the month

In this month's tip we will demonstrate how to create a new IRB application/protocol in 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

February 2016

eIRB Tip of the Month- February 2016 **Creating a new application/protocol***

In this month's tip we will demonstrate how to create a new IRB application/protocol in eIRB. For the purposes of this tip "application", "form", and "protocol" will be used interchangeably.

Before beginning an application:

- It's important to know what form you will need - the forms are not interchangeable and the IRB may or may not be able to offer flexibility if the wrong form is submitted (see #2 below).
- Investigators who wish to conduct research, as well as every member of a research team, must complete mandatory human subjects research training before a study can be approved; more information can be found on the IRB's Training and Education webpage.

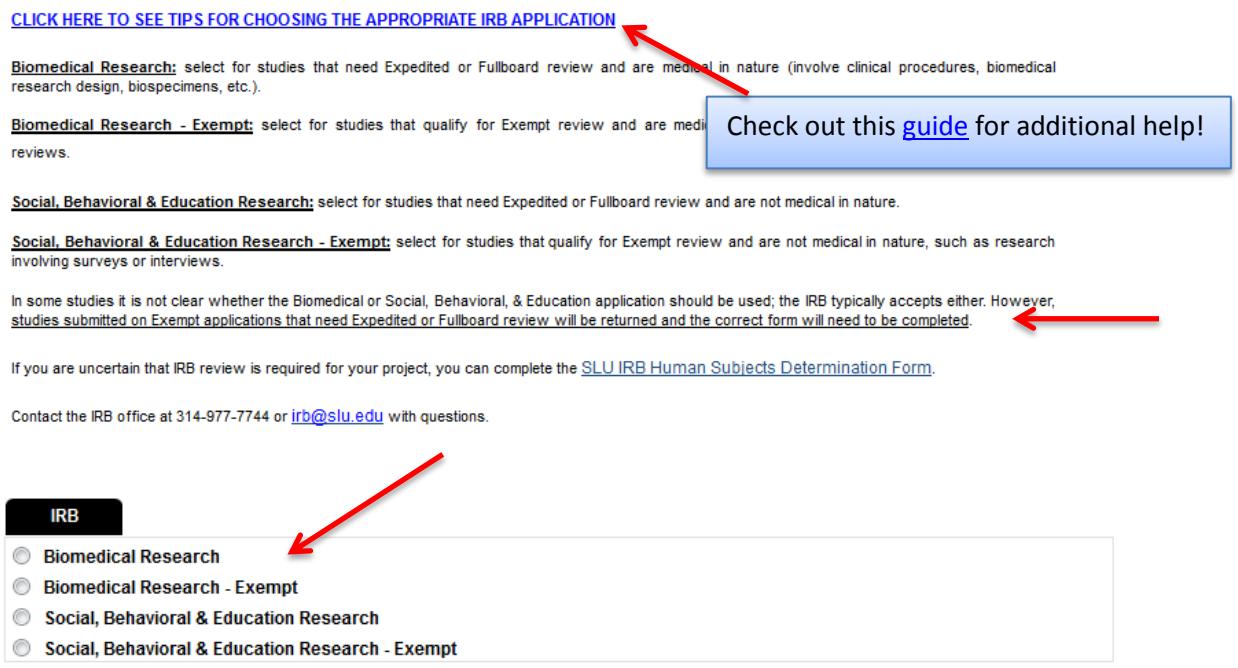
Important system reminders:

- The eIRB system does not work properly in Google Chrome; ensure that you access the system using recommended versions of Internet Explorer, Mozilla Firefox, or Safari as detailed on the homepage.
- Make sure that you have pop-up blocker turned off, as eIRB functions in pop-up format. See the eIRB tip for disabling pop-up blocker on the IRB's website for instruction in your selected browser.

Follow the steps below to create a protocol:

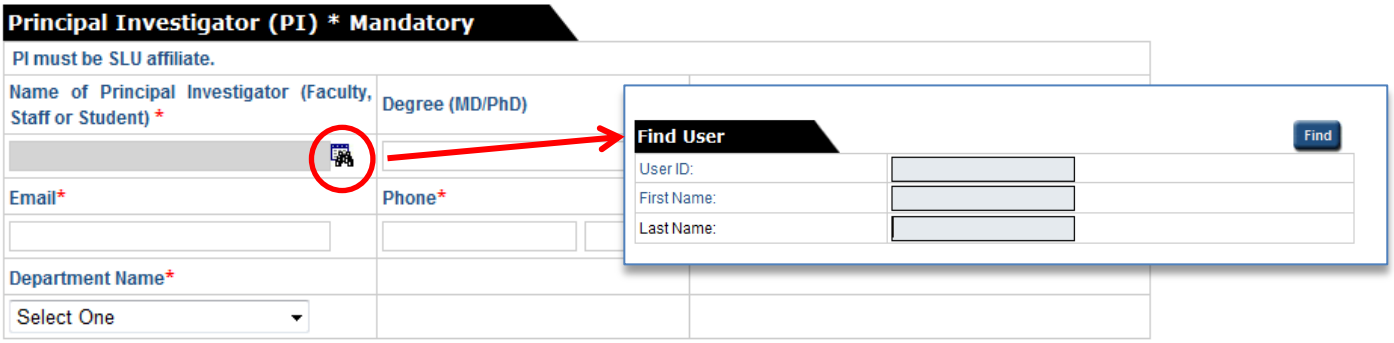
1. Click Create Protocol, located at the top right of your Investigator Dashboard in eIRB. On the page that follows, enter the study title. A title must be given to the protocol in order to move forward on the creation page. The title may be changed later if needed.

2. Choose from the four available IRB protocol types by selecting the corresponding button; if you are unsure of which application to use, consult the application descriptions on the creation page.

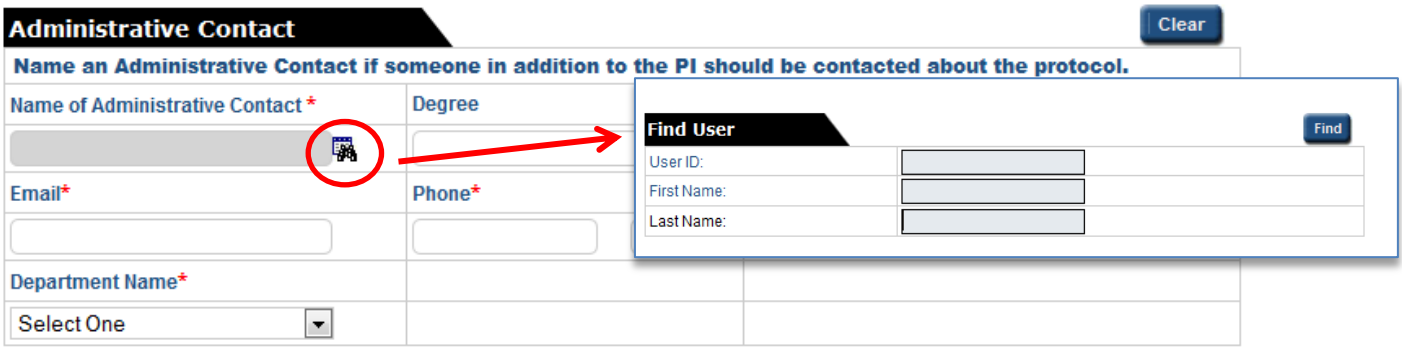


3. Once you've selected your form type the page will display two roles: Principal Investigator (PI) and Administrative Contact. The PI must be listed at the time of protocol creation. However, it is not mandatory to list an Administrative Contact unless the person creating the protocol is not the PI (i.e., the logged-in user must be listed in one of these two roles in order to create the protocol).

a. Click the bionoculars icon to search for and select the PI. For tips on searching for users, click here.



The PI accepts responsibility for the study, must sign the PI Obligations, and can edit/submit the protocol.



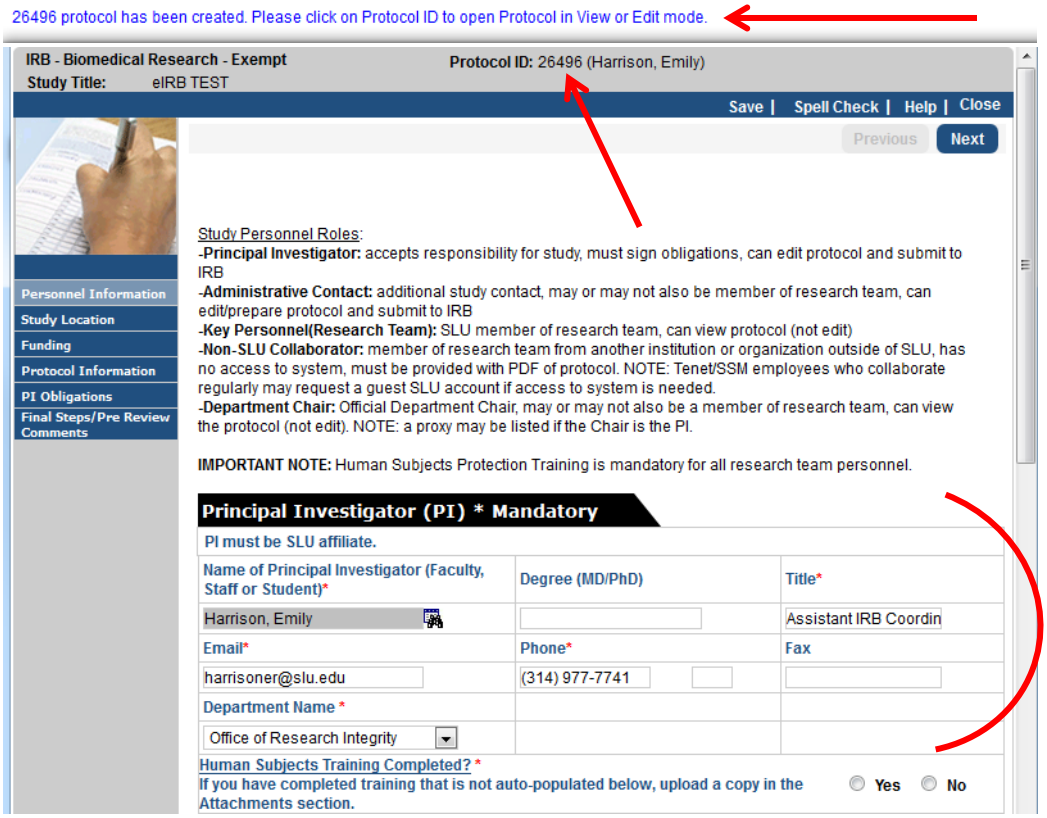
b. A Research Coordinator, Assistant, or Co-Investigator (listed as Administrative Contact) may create the protocol by listing themselves in the Administrative Contact role. If you are creating a protocol on behalf of a PI, list yourself in the Administrative Contact box.

Additional Administrative Contacts can be added later. The user in this role may or may not also be a member of the research team, and will be able to edit/submit.

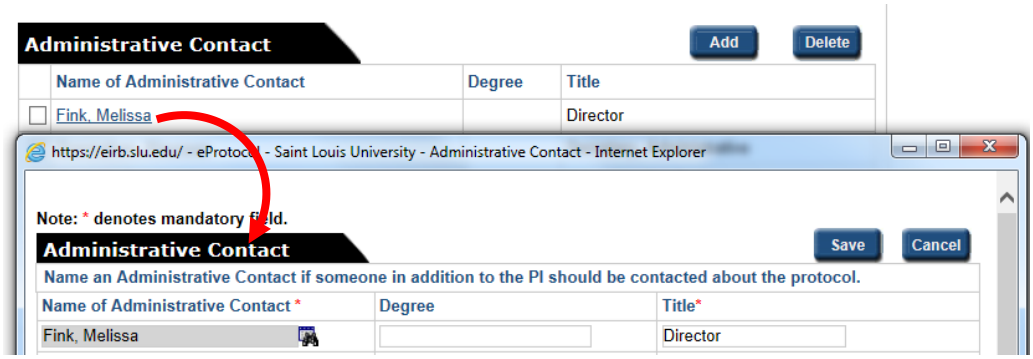
Members of the research team who do not need to edit should be listed as Key Personnel and will only have view capability.

c. When you have selected the PI (and Administrative Contact(s) if available) and answered all required fields, click Create Protocol at the bottom or top of the section.

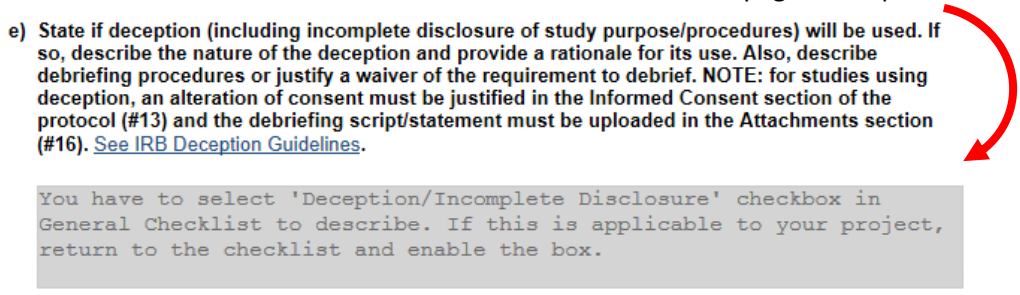
4. The newly created IRB protocol will generate in a pop-up window and you will be given a unique Protocol ID number (IRB #) that can be found at the top of the form or on the dashboard. The IRB number is helpful when contacting the IRB Office with questions.



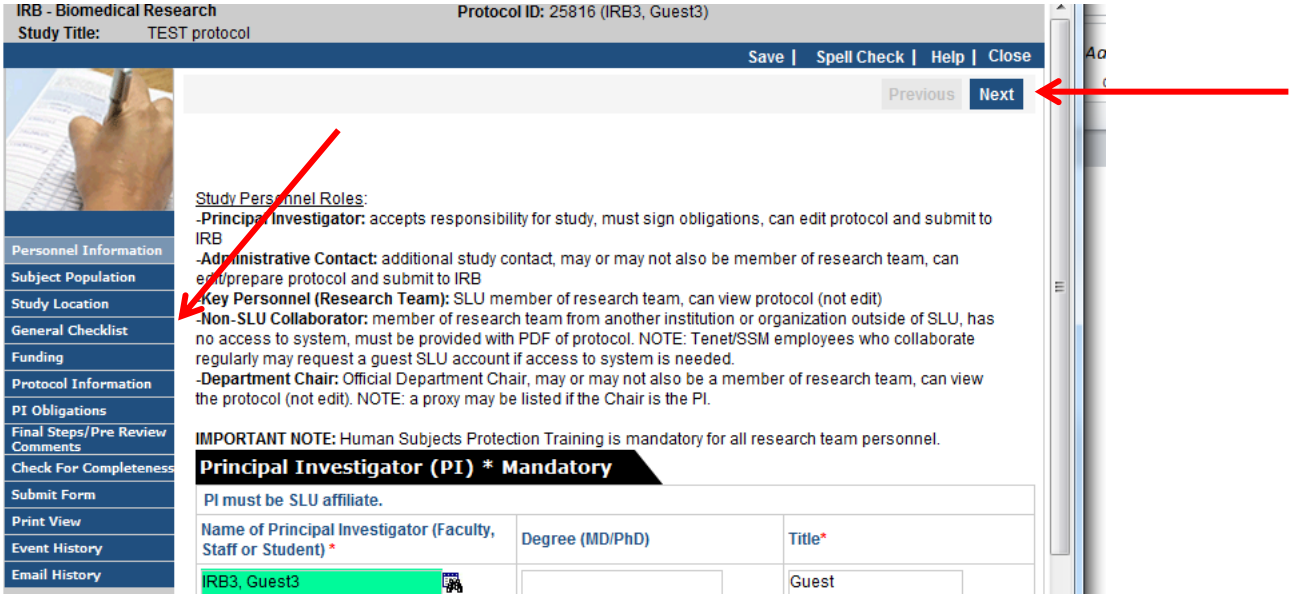
Personnel information entered on the creation page will be included in this section of the form. For each user who was listed on the creation page, you will be required to answer additional questions to complete the person's record. For the Administrative Contact, click on the person's name to view the additional questions.



5. The first 2-4 pages of any application are mandatory (depending on whether the protocol is Exempt or Expedited/Full), which helps eIRB customize your form. Some questions and sections of the form are inactive and do not have to be answered unless activated in a checklist on the first pages. Complete mandatory pages before move freely.



6. The protocol's sections are listed in the left-hand side of the application in the blue menu; click on these sections enter study information. Navigate within the protocol by using the blue bars or the "previous" and "next" buttons at the top or bottom of each page.



7. **As you complete the application**:

a) Save often; the Save feature is located in the upper-right hand side of the protocol.

b) You can complete the application by directly typing or copying & pasting text. Be aware that copying & pasting text containing symbols or special formatting may not translate directly. Copying and pasting into a Word document first (and then into the eIRB form) may help resolve symbol or formatting translation issues.

c) Some sections of the application are equipped with links to instructions, definitions, and supplemental documents to help the user; click directly on the link or on *?HELP?* for guidance. *?HELP?* links contain either application considerations or ethical considerations, to help you to know what type of response the IRB is looking for to that particular question on the form.

d) Some departments at SLU have specific requirements for who should be listed in the Personnel Information page and who should conduct the pre-review(s). This document is found on the IRB's website and in the system's pre-review instructions.

Department/Division-Specific New Protocol Submission Requirements

e) Click on the Check For Completeness located in the left menu of blue bars to ensure that all required protocol sections are answered. When the 'Check for Completeness' pop-up window displays the message 'The IRB application is complete', the new application is ready to be submitted for pre-review. Helpful instruction on completing the pre-review process can be found in a 5-minute video located at the bottom of the Investigator dashboard in eIRB.

f) Click Print View to generate a full or partial PDF of the protocol. PDFs can be sent to reviewers to aid in the pre-review process, or to Non-SLU Collaborators who do not have eIRB system access.

g) To check the status of the protocol, click Event History, Email History, or see the protocol event status on your dashboard.

h) The PI and all listed Administrative Contacts will receive email notifications as the protocol moves through the process to approval. Notifications which require action by the study team are marked with ***Action Necessary***.

i) If you have additional questions as you are filling out the new protocol, contact your department's IRB Coordinator.

* This tip was prepared in February 2016. 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.