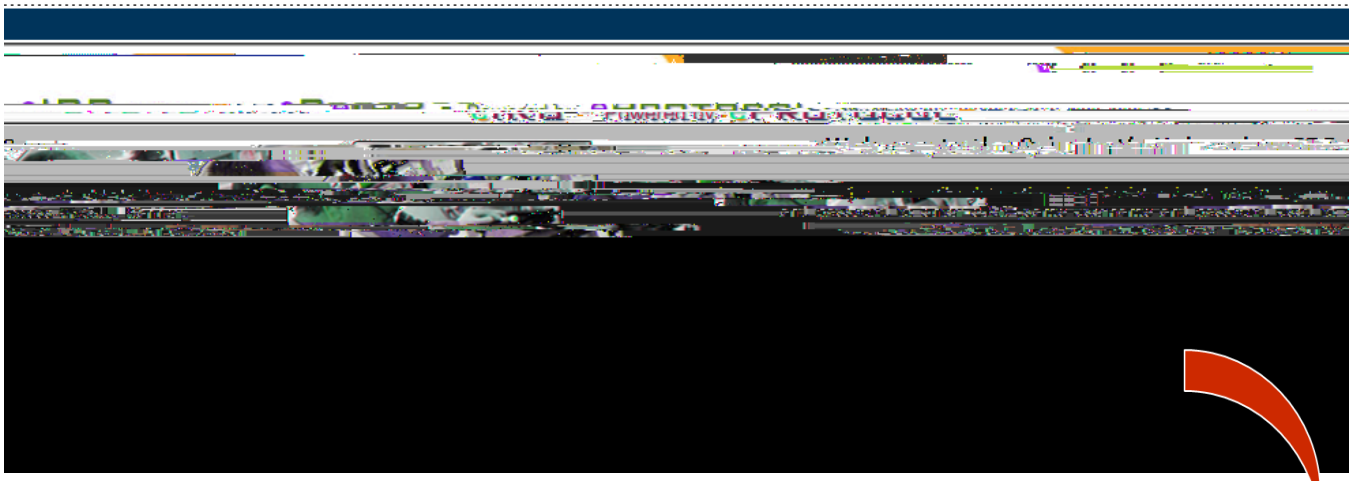
How do I access eIRB?



1. Log on to:http://eirb.slu.edu at any computer
2. Use the same information to log in to eIRB that you use to log in to your work computer or your MySLU account.

   User ID = SLU Net ID: lastname@slu.edu

NOTE: When your MySLU password is changed, it will automatically change for eIRB.

Before getting started

- **Allow pop-up windows**
  Turn off pop-up blocking software for the eIRB site in order to allow certain windows within the application (including forms, next steps, etc) to open. You may need to do this more than once. For more information on how to disable pop-up blocking software, see page 15.
- **$YRLG XVLQJ \RXU EURZVHU·V %$&. EXWWRQ**
  Using the BACK button could cause the system to time out and log you off. Instead, use

The Dashboard/Homepage

- The Investigator Dashboard or Homepage is a catalog of protocols:
  1) **In Preparation/Submitted** – Forms separated by type (e.g., New, Amendment, Continuing Review, etc.) that have not yet been submitted to the IRB for review or have been submitted to the IRB but have not yet been approved.
  2) **Pre-Reviews** – Submissions that are waiting to be pre-reviewed by the Department Chair/Advisor and the Scientific/PPC Reviewer (if applicable).
  3) **Approved Protocols** – Protocols that have been approved by the IRB and are active and open. Subsequent forms (Amendment, Continuing Review, etc.) can be created from this section of the dashboard.
  4) **Non Active Protocols** – Approved protocols that have expired or have been closed.

NOTE

Dashboard Actions to Take

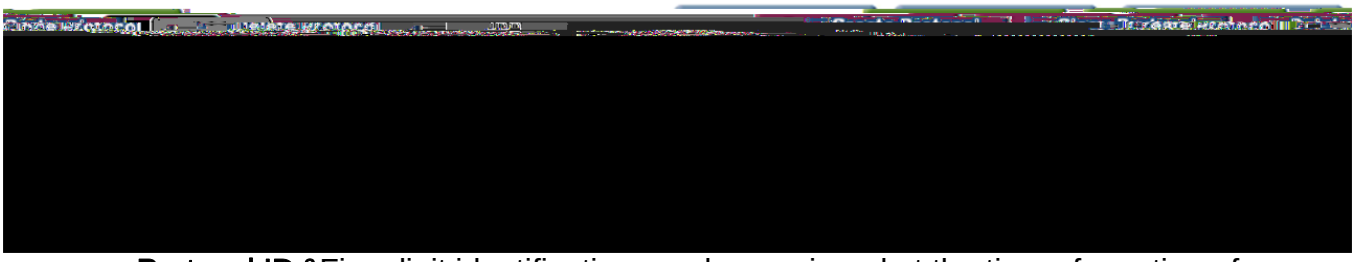
Use the left navigation drop down Investigator Menu or the blue action buttons to work within the system.

- Investigator Menu Selections:
  - **Approved Protocols**² A list of all approved protocols. Subsequent forms (i.e., Continuing Review, Amendment, etc.) can be created from this section by clicking or selecting the Protocol ID # link.
  - **Clone Protocol**² A list of protocols that can be copied. An exact copy of a protocol (with a new Protocol ID #) will be created by selecting the protocol and cloning (see below). NOTE: Remember to change the title and other details on the new protocol as needed.

○	20031	Millinger, Rachel		Pre-Review Required	NEW		

  - **Create Protocol**² Create a new application/form by clicking or selecting create protocol.
  - **Delete Protocol**² $ O L V W R I ´ , Q 3 U H S D U D W L R Q µ Q H Z S U R W R F R O V R Review, Serious Adverse Event Form, etc.) that can be deleted. Forms that have not yet been submitted to the IRB may be deleted from the system.
  - **Investigator Home**² Selecting this will return you to the Investigator dashboard/homepage.
  - **Search Protocol**² On this screen an investigator may search all protocols on which they are a member of the research team. Protocols can be searched by Title, PI Name, Protocol ID and

Dashboard/Homepage Terms



- Protocol ID [2] Five digit identification number assigned at the time of creation of a new application. The Protocol ID is equivalent to the IRB number that is currently assigned when a protocol is received in the IRB office. In the eIRB system the number will be assigned as soon as the protocol is created.
- Principal Investigator [2] The PI listed on the protocol. The PI must be a SLU affiliate. Only one PI can be listed.
- Department Name [2] The department affiliation of the Principal Investigator (PI).
- Protocol Event [2] The current status of the protocol. Clicking the link will either open the protocol or begin the next action needed. See page 14 for more information about the meanings of different events.
- Panel

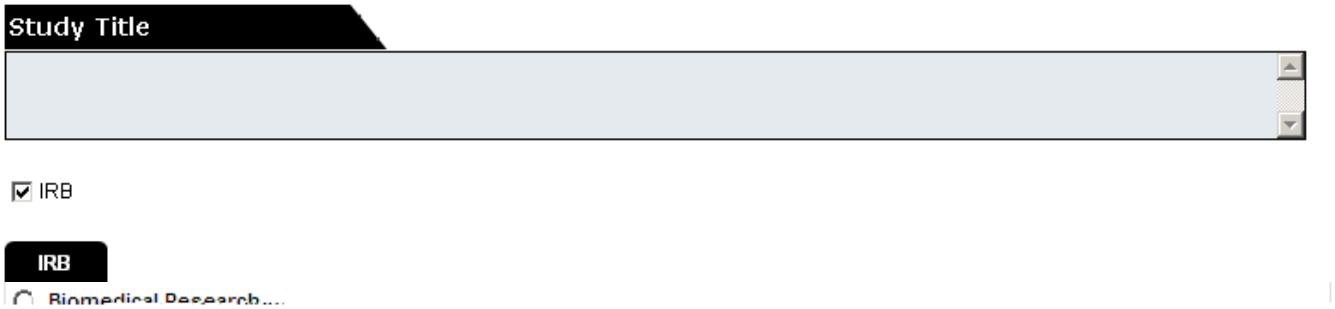
Creating a New Protocol

1. &OLFN WKH ´&UHDWH 3URWRFROµ EXWWRQ RU VHOHFW LW

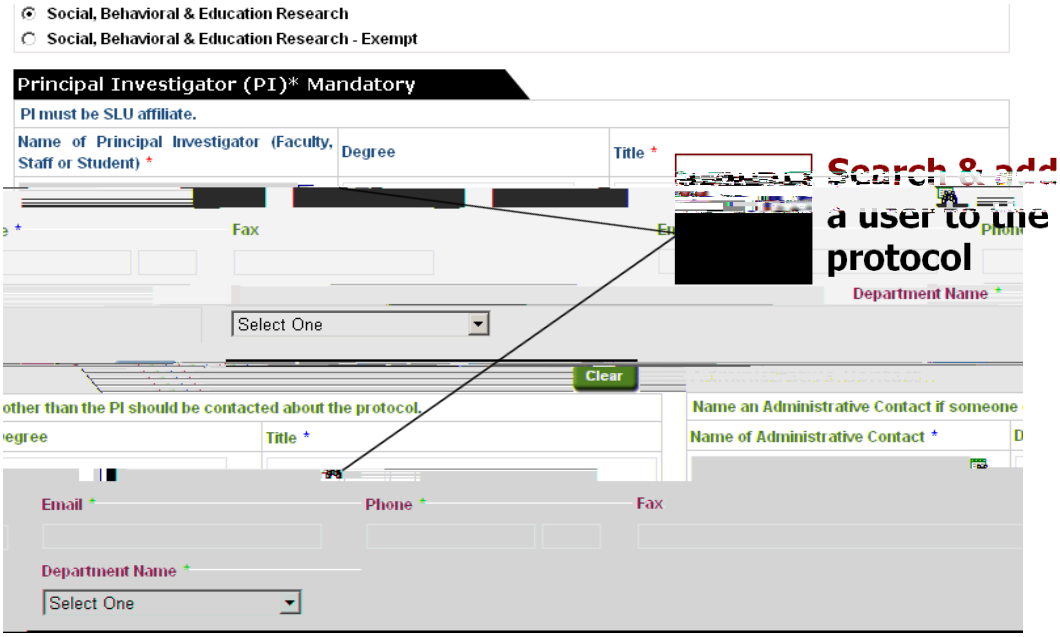
2. Enter the title of your study.

3. Select a form from the options available. Decide whether you will apply for an Exempt or an Expedited/Full Board review. Expedited and Full Board protocols will use the same form (the Expedited justification has been incorporated as one page of the full form). Both forms are different and are not interchangeable.

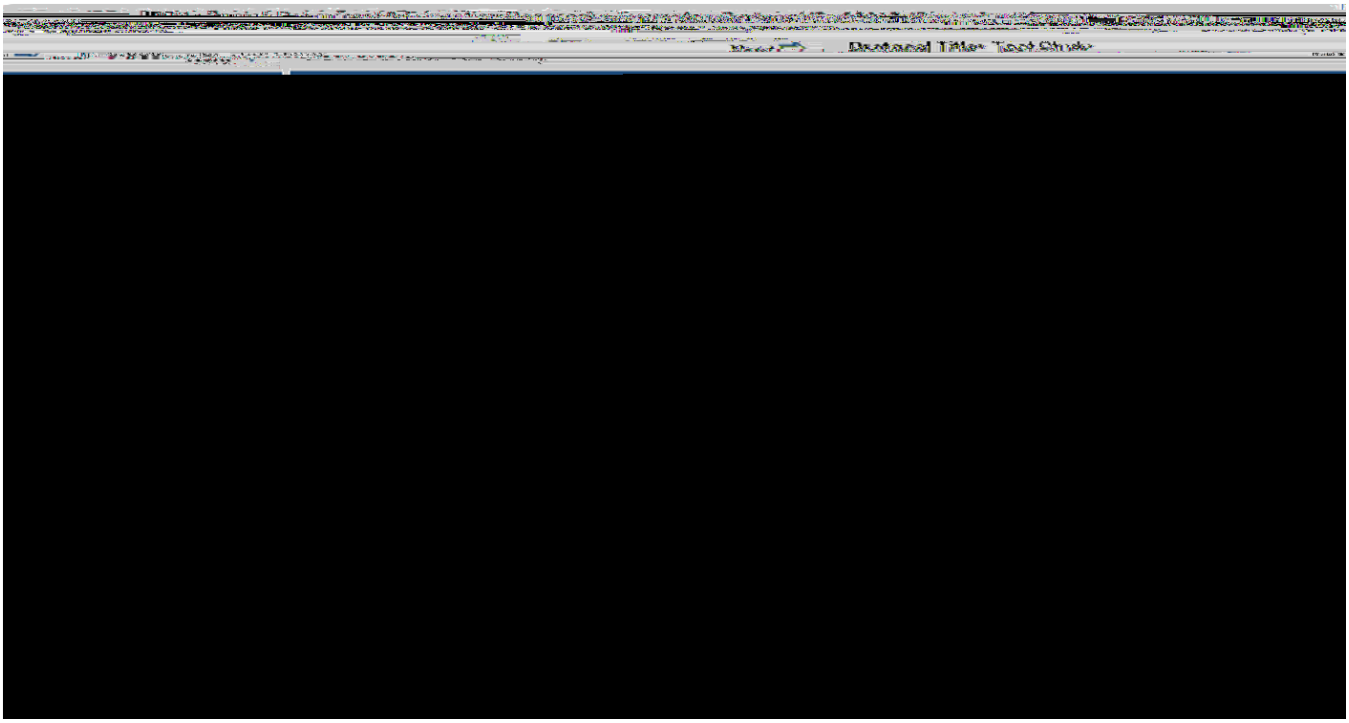
   NOTE : Researchers may not make an independent determination of whether a research study is exempt. Exempt does not mean that your research does not need IRB review. All exempt studies are initially reviewed by the IRB. Only the IRB can determine whether or not a study qualifies as exempt.



4. Search and add the Principal Investigator to the protocol. A Principal Investigator (PI) must be named at the time of the creation of the form. A Research Coordinator or Assistant may search and add a PI to the protocol and then add themselves as the Administrative Contact. An Administrative Contact is not required to begin a protocol.
   NOTE : The loggedin user must be added to the protocol as either the PI or the Administrative Contact in order to continue with the form.



Completing the Form

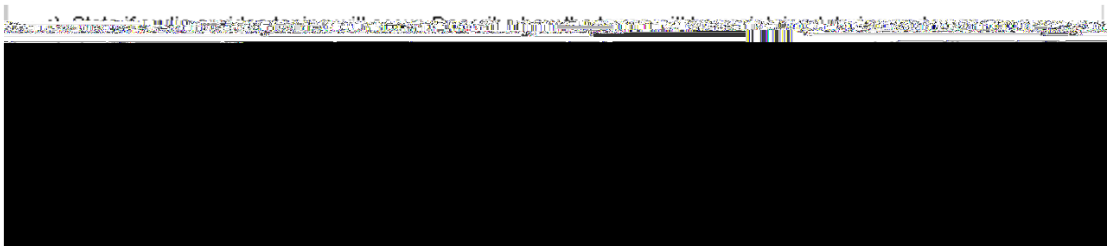


- Use the blue navigation menu on the left or the arrows on the right to navigate through form.

- Sections of the Form:
  - Personnel Information: Comparable to section A of the full paper form. Use this section to add all the members of the research team based on their individual roles. See page 14 for more details on team member roles. NOTE: More than one Administrative Contact, Key Personnel (Research Team), and Non-SLU Collaborator may be added to the protocol.
  - Protocol Information: This navigation tab contains the main pages of each form. The sub pages can be navigated by clicking on the tabs at the top of that page.
  - PI Obligations: The signature page where the PI will answer two questions regarding Conflicts of Interest and provide an electronic signature and assurance. NOTE: Only the PI can answer these questions and submit the protocol.
  - Final Steps: This page describes the final steps needed before the protocol can be submitted to the IRB. These steps include the electronic signature of the Department Chair/ Advisor (or an official proxy), the Scientific/PPC Reviewer, etc.
  - Check for Completeness: A check that all mandatory fields are completed.
  - Submit Form: The PI can initiate the Department Chair/Advisor and Scientific/PPC

Completing the Form

Some questions and sections of the form are inactive and cannot be answered unless activated in another section of the application (usually a checklist at the beginning of the form).



Attaching Documents

Some documents should be uploaded directly onto the corresponding page of the form. All

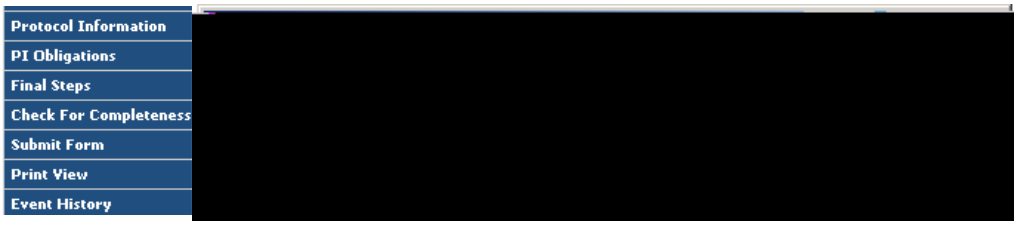
Templates for necessary supplemental documents (e Informed Consent, Recruitment Statement, etc.) are linked within the form or are available on the IRB website.

Required Pre Reviews

Before the protocol can be submitted to the IRB, a Scientific/PPC Review **AND** a Department Chair/Advisor review (signature) is needed (unless noted below). Both reviews will happen within the system.

Scientific/PPC Review:

- A Scientific/PPC Review is needed for all investigator initiated protocols. Pharmaceutical sponsored trials and Biomedical Exempt protocols are **NOT** required to undergo this review.
- At least one scientific review is required. **NOTE:** The reviewer cannot be a member of the research team or the Department Chair/Advisor.
-)ROORZ \RXU GHSDUWPHQW·V 6FLHQWLILF 33& 5HYLH ROL GHWHUPLQH KRZ WR REWDLQ DSSURYDO RU UHIHU W KH IRB website for more information on this review.



Responding to Contingencies

1. The PI and Administrative Contact(s) will be notified by the system with an e-mail when the IRB has returned a protocol with contingencies. The Protocol Event on the Investigator 'DVKERDUG ZLOO FKDQJH WR VD\ ´&RPPHQWV 5HFHLYHG &

20031	Fink, Melissa	Anesthesiology	Comments Received (Cycle 1)

2. Click on the Protocol Event Link to bring up the comments/contingencies page.

3. 5HYLHZ WKH FRPPHQWV &OLFNLQJ ´6KRZ $OO &RPP WVµ comments.

4. &RPPHQWV VKRXOG EH DGGUHVVHG ZLWKLQ WKH IR E\ F required changes.

5. Comments should also be addressed in the response box on the comments/contingencie page.

NOTE : The comments page replaces the response to contingency letter that was required with pape forms. Highlighting changes in the protocol is also no longer needed. However, uploaded documents with changes will still need to be highlighted. Documents in PDF format that are changed need to be uploaded once with highlighted changes and again as a clean copy for IRB approval stamping.

6. When changes have been made in the protocol and all comments have been given a response, FOLFN ´6XEPLW WR ,5%µ WR VXEPLW FRPPHQWV 7KH 3URW ´5HVSRQVHV 6HQW &\FOH µ

20024	Fink, Melissa	African-American Studies	Responses Sent (Cycle 1)	[redacted]	08/09/2010

The Event & Email History

The last two tabs of the protocol contains a log of every event and system generated email associated with the life of the protocol.**NOTE**