SLU eIRB– Pre-Reviewer Guide

Saint Louis University

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Behavioral & Biomedical (BSS & BIO) eIRB Pilot

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Pre-Reviewer Guide

February 2011

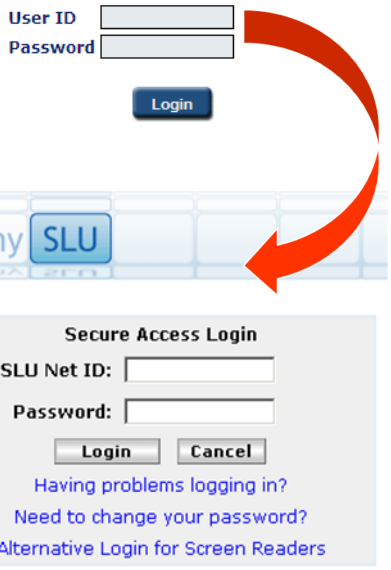
eIRB - Powered by ePROTOCOL

http://eirb.slu.edu

Institutional Review Board
Saint Louis University
Caroline Building, Room C110
3556 Caroline St.
St. Louis, MO 63104
(314) 977-7744
(314) 977-7730 (fax)
http://www.slu.edu/x24634.xml

SAINT LOUIS UNIVERSITY

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.

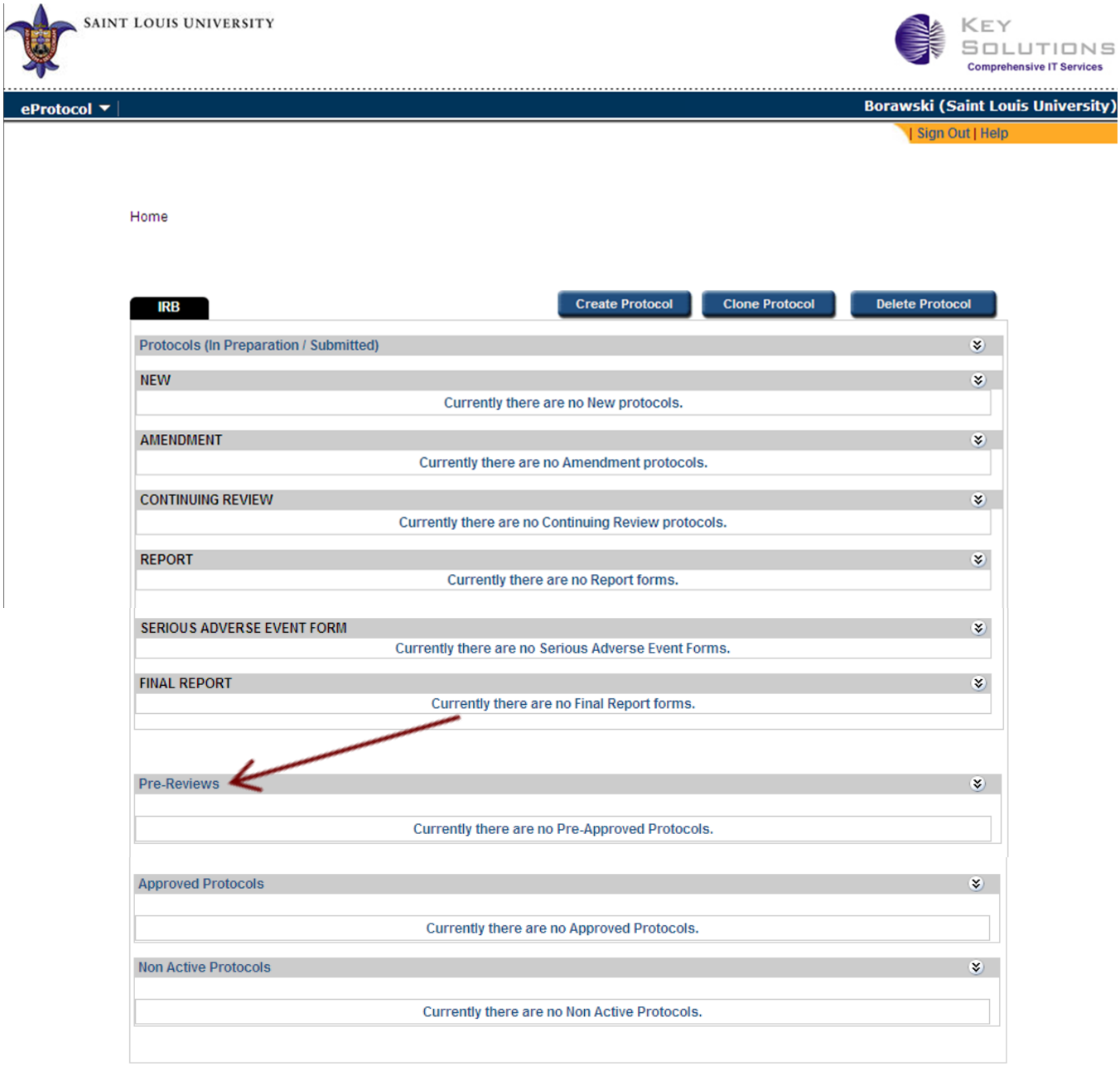
User ID = SLU Net ID: lastname@slu.edu

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. For more information on how to disable pop-up blocking software, see page 7.
- **Avoid using your browser's BACK button**
  Using the BACK button could cause the system to time out and log you off. Instead, use the navigations within the system and forms to move around.
- **Choose your browser**
  The eIRB system is compatible with Internet Explorer, Mozilla Firefox, and Safari. Choose the browser you are most comfortable with.
- **Save frequently**
  eIRB will time out after 45-60 minutes of inactivity. The system will automatically save your work after some actions in the system (e.g., moving to the next page in a form). However, saving frequently will protect the information you have entered during the session.
- **Read the help and instruction**
  Help content is available within the application and on the eIRB section of the website. Online help video modules, live classes, and system support will be available during the eIRB pilot. Coming soon!

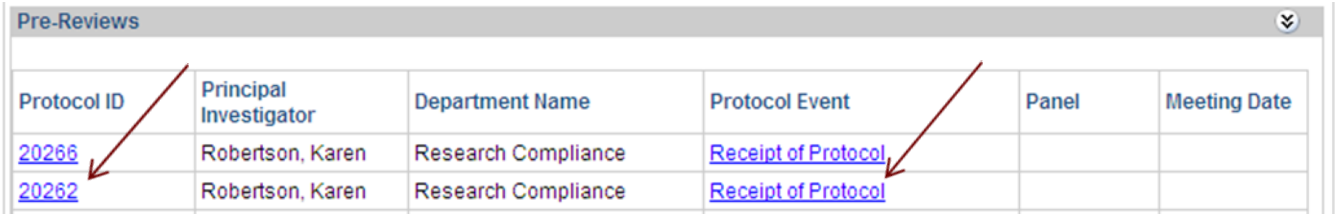
The Dashboard/Homepage



- The Investigator dashboard/homepage is a catalog of all protocols where you are listed as the PI, a member of the research team, or the Department Chair/Advisor. See the Investigator guide for more information about the dashboard/homepage.

- Pre-Reviewers (the Department Chair/Advisor/Proxy OR the Scientific/PPC Reviewer) will find protocols assigned to them for review in the "Pre-Reviews" section of their dashboard. **The focus of the pre-reviewer should only be in the "Pre-Reviews" section to complete the review.**

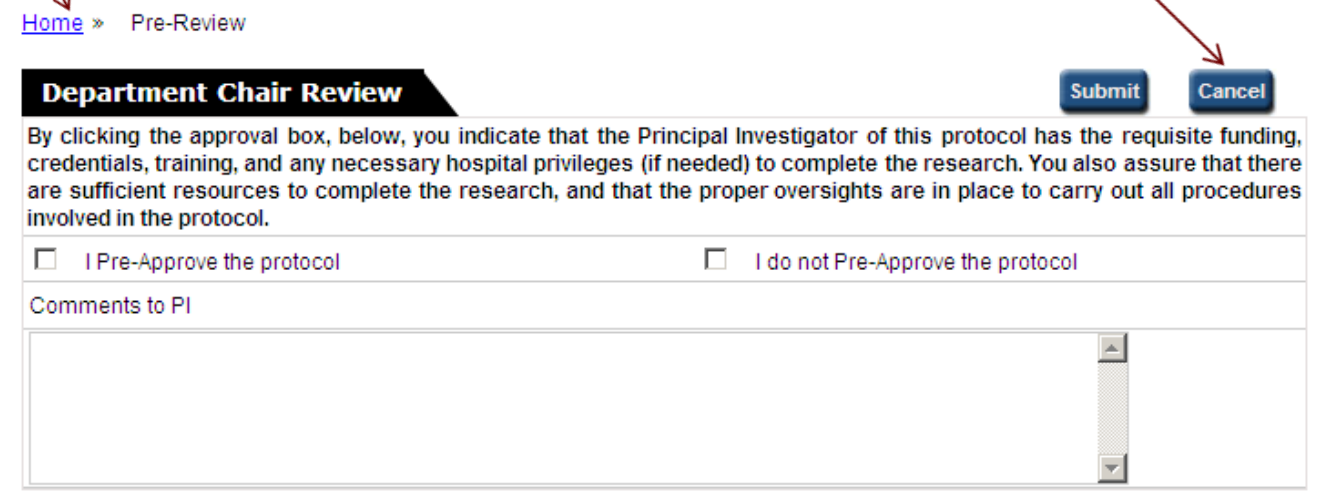
Reviewing the Protocol



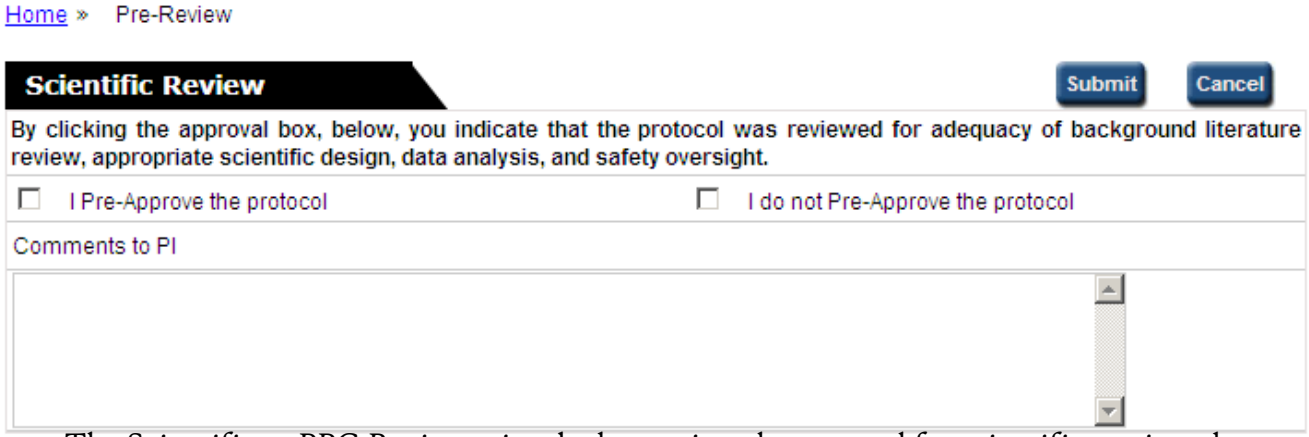
- The user assigned as either pre-reviewer will get an e-mail notification stating that the protocol is ready to be reviewed once the PI has selected the pre-reviewer(s) and submitted the protocol. The Protocol Event in the "Pre-Reviews" section will read, "Receipt of Protocol".

1. To view the protocol, click on the "Protocol ID" link.
2. When you are ready to make your comments and return the protocol to the PI, click the "Receipt of Protocol" link under the Protocol Event column to start the process.

   NOTE: Once on the comments screen, you will be able to cancel or return to the dashboard/ homepage in order to review the protocol but you will not be able to directly access the protocol from that page. (We are working on that during pilot!). [Steps 3, 4 cont. on page 5]



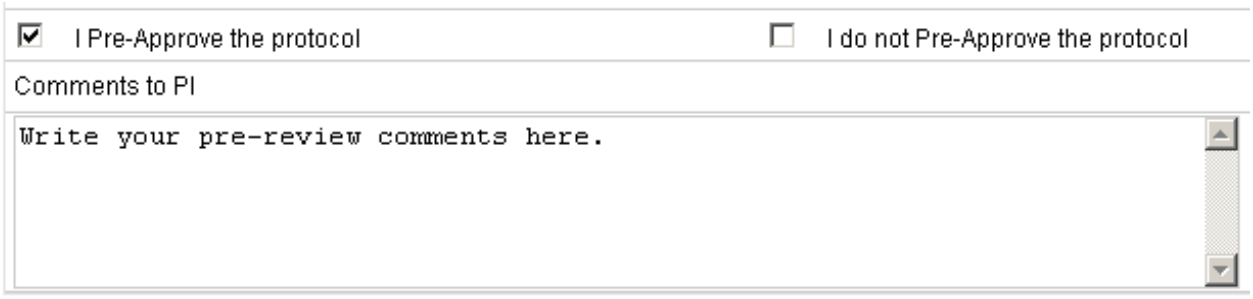
- The Department Chair, Advisor, or official Proxy is asked to review the protocol and electronically "sign" the assurances box (above). This replaces the signature on the first page of the IRB paper application page.



- The Scientific or PPC Reviewer is asked to review the protocol for scientific merit and electronically "sign" the assurances box (above). This replaces the paper form "Scientific Review Form For Investigator Initiated Studies".

Signing the Assurances

3. Add your comments/requests to the PI in the text box (box will expand) and mark whether or not you approve the protocol.



- WARNING: If you mark "I do not Pre-Approve the protocol" the PI will not be able to submit the protocol and will need to start a new submission and re-submit for pre-approval.

4. When you've finished making your comments, have selected whether or not you pre-approve the protocol, and are ready to return the protocol "signed" to the PI– click the Submit button to finish.

- NOTE: Protocols will drop from the "Pre-Approvals" section when your review is completed. If both a Department Chair/Advisor Review and a Scientific/PPC Review were required and assigned, the protocol event status will change to say "Pre-Reviewed" and will drop from the "Pre-Approvals" section when BOTH reviews are completed and returned to the PI.

Glossary of Terms

- Protocol Events for Pre-Reviews dashboard section:
  - **Receipt of Protocol**– The protocol has been assigned to the pre-reviewer and is waiting to be reviewed.
  - **Pre-Reviewed**– The protocol which was assigned to both a Department Chair/Advisor and a Scientific/PPC Reviewer has been reviewed by one pre-reviewer and the other review is still outstanding.

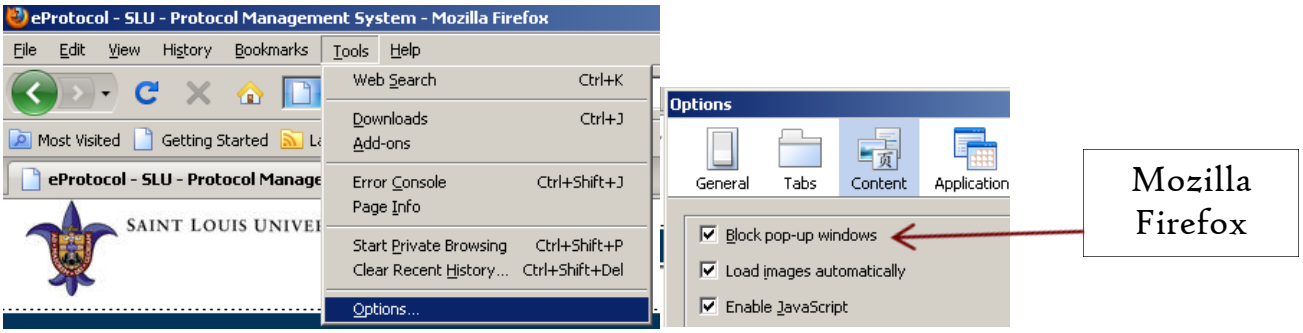
- Personnel Roles:
  - **Principal Investigator**– The investigator who accepts responsibility for the research study and its team members, monitors on-going compliance, and completes the subsequent paperwork for the protocol. This role has edit and view rights.
  - **Administrative Contact**– Team member responsible for completing parts of the IRB form, who may or may not have additional responsibilities as part of the research team. Additional questions need to be answered when this role is also a member of the research team. This role has edit and view rights.
  - **Key Personnel (Research Team)**– Members of the research team who do not need editing rights to the protocol. This role has view rights only.
  - **Non-SLU Collaborator**– Members of the research team who are not affiliated with Saint Louis University. Documentation of Human Subjects training will need to be uploaded in the Attachments section for team members with this role. This role does not have edit or view rights.
  - **Department Chair/Advisor**– Individual (who may or may not also be part of the research team) with administrative signature rights to assure that the affiliated department has adequate resources to conduct the research. This role has view rights only.

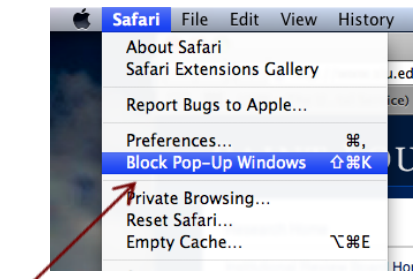
    NOTE: Biomedical protocols should list the officially named Department Chair in the Personnel Information section of the protocol. If a proxy will sign the protocol in lieu of the officially named Department Chair, that user will be named by the PI when the review is assigned.

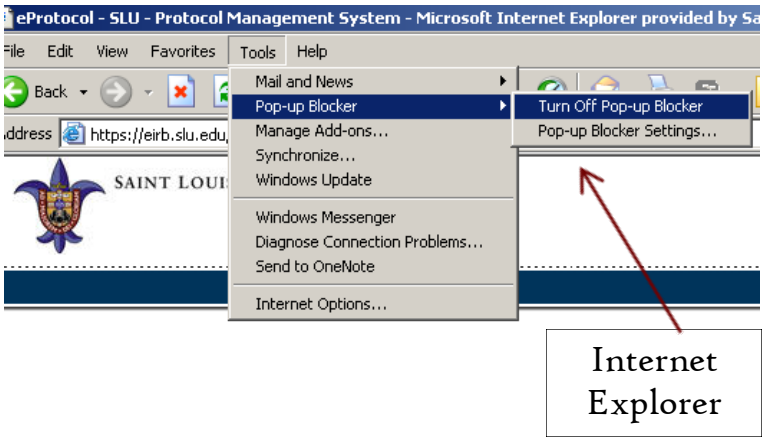
Disabling Pop-Up Blocker

Disabling pop-up blocker on your browser will allow forms and permission screens to work for eIRB. Internet Explorer, Mozilla Firefox and Safari allow pop-ups to be disabled in either the following menus:

- Internet Explorer— Tools > Pop-up Blocker > Turn Off Pop-up Blocker
- Firefox— Tools > Options > Content > Block pop-up windows
- Safari— Safari > Block Pop-Up Windows







Help and Support?!?!

During the BSS & BIO eIRB pilots help and support are available in existing documents on the IRB website, in help content within the system, through help and FAQ documents and video modules coming soon to the website, and by live support.

<u>Live support:</u>

Melissa Fink
(314) 977-9814
gibbonsm@slu.edu

Rachel Millinger
(314) 977-9813
millinrm@slu.edu

<u>IRB website:</u>
http://www.slu.edu/x24634.xml