

Saint Louis University

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eIRB

Investigator  
Submitter Guide

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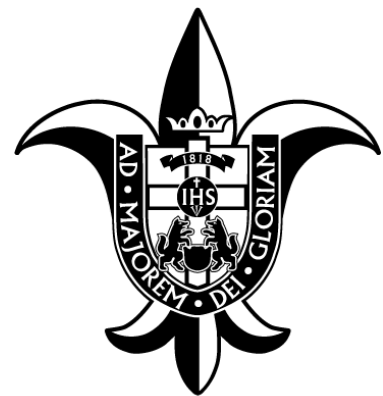
Institutional Review Board

June 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?

## eIRB - Powered by ePROTOCOL Welcome to the Saint Louis University eIRB System

The eIRB system is open to all Saint Louis University investigators. Please use your SLU Net ID and password to enter eIRB (same username and password used to access MySLU, Banner, etc). Non-SLU (guest) users can request system access, and may be granted it under certain circumstances. Contact [irb@slu.edu](mailto:irb@slu.edu) with access issues.

All new IRB protocols should be submitted in the eIRB system. Subsequent amendments, safety reporting and continuing review of those new eIRB protocols should also be submitted. All other protocol activity must be conducted via SLU IRB paper forms until further notice.

Note: In eIRB only, the deadline for submitting protocols for meeting dates is extended from 3pm on the deadline day to midnight. Meeting dates and corresponding submission deadlines are posted on the IRB website.

For training materials or more information: Go to <http://www.slu.edu/x30683.xml>.



User ID   
 Password



Secure Access Login  
 SLU Net ID:   
 Password:   
   
[Having problems logging in?](#)  
[Need to change your password?](#)  
[Alternative Login for Screen Readers](#)

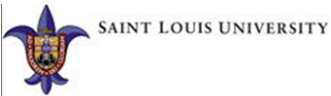
1. Log on to: <http://eirb.slu.edu> at any computer
2. Use the same information to log in to eIRB that you use to log in to your work computer or your MySLU account.

User ID = SLU Net ID:

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.
- **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 (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 are available to help you. Visit the eIRB website ([www.slu.edu/x30683.xml](http://www.slu.edu/x30683.xml)) or call the main office (314-977-7744).



Home

**IRB** [Create Protocol](#) [Clone Protocol](#) [Delete Protocol](#)

|   |   |
|---|---|
| <b>Protocols (In Preparation / Submitted)</b>       | ▼ |
| <b>NEW</b>  | ▼ |
| Currently there are no New protocols.               |   |
| <b>AMENDMENT</b>                                    | ▼ |
| Currently there are no Amendment protocols.         |   |
| <b>CONTINUING REVIEW</b>                            | ▼ |
| Currently there are no Continuing Review protocols. |   |
| <b>REPORT</b>                                       | ▼ |
| Currently there are no Report forms.                |   |
| <b>SERIOUS ADVERSE EVENT FORM</b>                   | ▼ |
| Currently there are no Serious Adverse Event Forms. |   |
| <b>FINAL REPORT</b>                                 | ▼ |
| Currently there are no Final Report forms.          |   |
| <b>Pre-Reviews</b>                                  | ▼ |
| Currently there are no Pre-Approved Protocols.      |   |
| <b>Approved Protocols</b>                           | ▼ |
| Currently there are no Approved Protocols.          |   |
| <b>Non Active Protocols</b>                         | ▼ |
| Currently there are no Non Active Protocols.        |   |

- 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:** Individuals will be able to see any protocol where they are listed as the Principal Investigator, another member of the research team, and/or the Department Chair/Advisor.

# Dashboard Actions to Take



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KEY SOLUTIONS  
Comprehensive IT Services

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

## Investigator Menu Selections:

- **Approved Protocols**– 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**– 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.

| Protocol ID           | Principal Investigator | Department Name | Protocol Event      | Form Type | Panel | Meeting Date |
|-----------------------|------------------------|-----------------|---------------------|-----------|-------|--------------|
| <a href="#">20031</a> | Millinger, Rachel      |                 | Pre-Review Required | NEW       |       |              |

- **Create Protocol**– Create a new application/form by clicking or selecting create protocol. Exempt applications= “Biomedical Research- Exempt” or “Social, Behavioral & Education Research- Exempt” Expedited or Full Board applications= “Biomedical Research” or “Social, Behavioral & Education Research”
- **Delete Protocol**– A list of “In Preparation” new protocols or new forms (e.g., Continuing 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**– Selecting this will return you to the Investigator dashboard/homepage.
- **Search Protocol**– 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 even Form Type. Searches can also be save for future use. Saved searches maintain the search criteria for faster subsequent searches.

|                        |                         |              |                         |
|------------------------|-------------------------|--------------|-------------------------|
| Protocol ID            | <input type="text"/>    | Study Title  | <input type="text"/>    |
| Principal Investigator | <input type="text"/>    | Investigator | <input type="text"/>    |
| Form Type              | -----Please Select----- | Panel        | -----Please Select----- |
| Meeting Date           | <input type="text"/>    | SLU eRS #    | <input type="text"/>    |

## Dashboard/Homepage Terms

| <b>IRB</b>                             |                        |                     |                                     |       |              | <a href="#">Create Protocol</a> | <a href="#">Clone Protocol</a> | <a href="#">Delete Protocol</a> |
|--|------------------------|---------------------|-------------------------------------|-------|--------------|---------------------------------|--------------------------------|---------------------------------|
| Protocols (In Preparation / Submitted) |                        |                     |                                     |       |              | ⌵                               |                                |                                 |
| NEW                                    |                        |                     |                                     |       |              | ⌵                               |                                |                                 |
| Protocol ID                            | Principal Investigator | Department Name     | Protocol Event                      | Panel | Meeting Date |                                 |                                |                                 |
| <a href="#">20017</a>                  | Reetz, Scott           | Research Compliance | <a href="#">Pre-Review Required</a> |       |              |                                 |                                |                                 |

- **Protocol ID**- 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**- The PI listed on the protocol. The PI must be a SLU affiliate. Only one PI can be listed.
- **Department Name**- The department affiliation of the Principal Investigator (PI).
- **Protocol Event**- 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**- The Board that the protocol has been assigned to will appear in this column. In the eIRB system the terms Panel and Board are equivalent (e.g., the BIO Board = the BIO Panel or the BSS Board = the BSS Panel).
- **Meeting Date**- The date of the meeting assigned to the protocol. Minimal risk protocols (Exempt and Expedited reviews) will still be assigned a meeting date for reporting purposes though those protocols do not go to a convened IRB meeting.

## Other Dashboard Tips

- A protocol can be accessed by clicking either the Protocol ID or Protocol Event link.
- The dashboard can be organized by any of the blue column titles (e.g., Protocol ID, Department Name, etc.). Click on the title to sort by that category.
- Sign out when you are done with a session to protect your private information and to allow the Administrative Contact(s) to work in a protocol if needed. Not signing out could cause a protocol to be “locked for editing” when accessed by another user.
- For a cleaner dashboard: Sections of the dashboard can be collapsed by clicking the down arrow icon on the right side of each title bar.
- The dashboard can be refreshed by clicking the black IRB title tab.

|                       |                               |
|-----------------------|-------------------------------|
| <b>Protocol ID</b>    | <b>Principal Investigator</b> |
| <a href="#">20017</a> | Reetz, Scott                  |

|              |   |
|--------------|---|
| Meeting Date | ⌵ |
|--------------|---|

|  |
|--|
| <b>IRB</b>                             |
| Protocols (In Preparation / Submitted) |

- The dashboard will display the logged-in user’s last name and the dashboard that is visible upon log-in. The default setting for all users is “Investigator”. Some users (such as IRB Board members) will have more than one role and each role has a separate dashboard/homepage.

|   |
|---|
| <b>George (Saint Louis University) - Investigator</b> |
| <a href="#">Sign Out</a>   <a href="#">Help</a>       |

## Creating a New Protocol

1. Click the "Create Protocol" button (or select it from the blue Investigator drop down menu).
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.

**Study Title**

IRB

**IRB**

- Biomedical Research
- Biomedical Research - Exempt
- Social, Behavioral & Education Research
- Social, Behavioral & Education Research - 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 logged-in user must be added to the protocol as either the PI or the Administrative Contact in order to continue with the form.

- Social, Behavioral & Education Research
- Social, Behavioral & Education Research - Exempt

**Principal Investigator (PI)\* Mandatory**

PI must be SLU affiliate.

|  |                      |                      |
|--|----------------------|----------------------|
| Name of Principal Investigator (Faculty, Staff or Student) * | Degree               | Title *              |
| <input type="text"/>   | <input type="text"/> | <input type="text"/> |
| Email *  | Phone *              | Fax                  |
| <input type="text"/>   | <input type="text"/> | <input type="text"/> |
| Department Name *  | Select One           |                      |

**Search & add a user to the protocol**

**Administrative Contact** Clear

Name an Administrative Contact if someone other than the PI should be contacted about the protocol.

|                                  |                      |                      |
|----------------------------------|----------------------|----------------------|
| Name of Administrative Contact * | Degree               | Title *              |
| <input type="text"/>             | <input type="text"/> | <input type="text"/> |
| Email *                          | Phone *              | Fax                  |
| <input type="text"/>             | <input type="text"/> | <input type="text"/> |
| Department Name *                | Select One           |                      |

# Completing the Form

IRB - Social, Behavioral & Education Research - Exempt Protocol ID: 20017 (Reetz, Scott)  
 Protocol Title: Test Study

Next →

✓ Spell Check ? Help Save Close

IMPORTANT NOTE: Only the Principal Investigator can submit the protocol, although the administrative contact(s) listed on the protocol can edit the protocol. Human Subjects Protection Training is mandatory for all research team members.

**Principal Investigator (PI)\* Mandatory**

PI must be SLU affiliate.

| Name of Principal Investigator (Faculty, Staff or Student) * | Degree         | Title *     |
|--|----------------|-------------|
| Reetz, Scott   |                | Coordinator |
| Email *  | Phone *        | Fax         |
| sreetz@slu.edu   | (314) 977-7734 |             |
| Department Name *  |                |             |
| Research Compliance  |                |             |

Human Subjects Training Completed? \*  
 If you have completed training that is not auto-populated below, upload a copy in the  Yes  No

- Use the blue navigation menu on the left or the arrows on the right to navigate through the 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 Reviewer (if needed) electronic signature process by clicking this tab. The form can be submitted to the IRB (by the PI only) after the signature of the Department Chair/ Advisor is completed (or both types of signature if required).
- **Print View**– PDF versions of any or all sections of the form or the form with comments can be generated with this tab.
- **Event History**– A catalog of dates in the life of the protocol and a list of all e-mail correspondence from the system are listed here. Through this tab you can access the approved supplemental documents, approval letter and past PDF versions of the protocol to be printed or saved.

## 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).

- c) State if audio or video taping will occur. Describe how the tapes will be maintained during and upon completion of the project. Describe what will become of the tapes after use (e.g., shown at scientific meetings, erased, etc.).

You have to select 'Filming, Video, or Voice-Recording Subjects' checkbox in General Checklist to describe. If this is applicable to your project, return to the checklist and enable the box.

### 4. Radioisotopes or Radiation Machines

Please note: For projects requiring radiation procedures, please contact the Institutional Review Board (IRB) Radiation Safety Committee (RSC). Radiation Guidance: [http://www.slu.edu/Documents/provost/irb/Radiation\\_Safety](http://www.slu.edu/Documents/provost/irb/Radiation_Safety)

- a) If applicable, summarize in lay language the radiographic associated with this protocol. (X-ray, fluoroscopy, CT, rad CT, radiation oncology, accelerator, Cyber Knife procedure)

### General Checklist

| Select All That Apply :             |   |
|-------------------------------------|---|
| <input type="checkbox"/>            | Collection of Specimens   |
| <input type="checkbox"/>            | Data collection via e-mail or the Internet  |
| <input type="checkbox"/>            | FDA Approved Device   |
| <input type="checkbox"/>            | FDA approved drugs, reagents, other chemicals administered to subjects or biologic products |
| <input checked="" type="checkbox"/> | Filming, Video, or Voice-Recording Subjects   |
| <input type="checkbox"/>            | Medical Records   |
| <input type="checkbox"/>            | Questionnaires and/or tests   |
| <input checked="" type="checkbox"/> | Radioisotopes/radiation-producing machines, even if standard of care                        |

## Attaching Documents

Some documents should be uploaded directly onto the corresponding page of the form. All other supplemental materials should be uploaded in the Attachments page of the form. **Please be aware document file names for all attachments will appear in the full IRB approval letter.**

Note: \* denotes mandatory field.

### Informed Consent

Title \*

Consent Type \*

Upload Consent Form/Document \*  Attachment

Upload your informed consent document. Use the [SLU Informed Consent Template](#) document. If more than one consent will be used (e.g., adult consent, parental consent documents with these headings to help distinguish them from one another.

**File Download**

Do you want to open or save this file?

Name: Biomedical\_Informed\_Consent\_Template.doc  
Type: Microsoft Office Word 97 - 2003 Document  
From: [www.slu.edu](http://www.slu.edu)

Always ask before opening this type of file

While files from the Internet can be useful, some files can potentially harm your computer. If you do not trust the source, do not open or save this file. [What's the risk?](#)

Templates for necessary supplemental documents (e.g., 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:

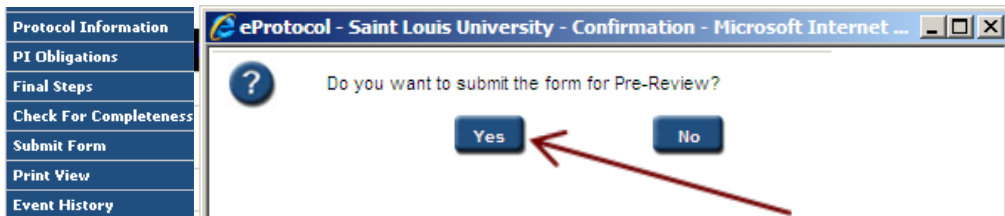
- A Scientific/PPC Review is needed for all investigator initiated protocols. Pharmaceutical sponsored trials and Biomedical Exempt protocols are **NOT** required to undergo this review.
- At least one scientific review is required. **NOTE:** The reviewer cannot be a member of the research team or the Department Chair/Advisor.
- Follow your department’s Scientific/PPC Review policies and procedures (if available) to determine how to obtain approval or refer to the “Guidelines for Scientific Review” on the IRB website for more information on this review.

### Department Chair/Advisor/Proxy Review:

- The Department Chair/Advisor review (signature) is required for all protocols submitted to the IRB.
- If the Department Chair/Advisor is unavailable to review the protocol or if an official proxy has been established for the department, the IRB will likely accept that review. Please call the IRB office (314-977-7744) for more information.

### To Start the Pre-Reviews:

- When the protocol is finalized, click on “Submit Form” in the blue navigation menu of the protocol. A window will open asking you if you want to submit the form for Pre-Review. Click “Yes” to start the process.



- Follow the instructions on the screen to select your Department Chair/Advisor and Scientific/PPC Reviewer. **NOTE:** If both types of review are required, you must select the reviewers at the SAME time. It is not possible to do the reviews one at a time in the system.
- Use the “Find User” button to search for the reviewer in each category.
- Be sure to check the box under “Pre-Review” to assign the review before submitting.

### Department Chair/Advisor/Proxy

| Name          | Department          | Email            | Phone Number   | Pre-Review               |
|---------------|---------------------|------------------|----------------|--------------------------|
| Fink, Melissa | Research Compliance | gibbonsm@slu.edu | (314) 977-9814 | <input type="checkbox"/> |

### Scientific/PPC Reviewer

| Name           | Department | Email             | Phone Number | Pre-Review               |
|----------------|------------|-------------------|--------------|--------------------------|
| IRB3, Amendola |            | gst-eirb3@slu.edu |              | <input type="checkbox"/> |

- The PI will get an e-mail notification when a pre-reviewer has completed the review. After the protocol is pre-reviewed by both reviewers (and any requested changes from the pre-review are addressed), open the protocol and click on “Submit Form” again to submit to the IRB. **NOTE:** Only the PI can submit the protocol.



## Responding to Contingencies

- 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 Dashboard will change to say, “Comments Received (Cycle 1)”.

|                       |               |                |   |
|-----------------------|---------------|----------------|---|
| <a href="#">20031</a> | Fink, Melissa | Anesthesiology | <a href="#">Comments Received (Cycle 1)</a> |
|-----------------------|---------------|----------------|---|

- Click on the Protocol Event Link to bring up the comments/contingencies page.
- Review the comments. Clicking “Show All Comments” will bring up a printable list of comments.
- Comments should be addressed within the form by clicking “Get Protocol” and making the required changes.
- Comments should also be addressed in the response box on the comments/contingencies page.

**NOTE:** The comments page replaces the response to contingency letter that was required with paper 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.

Protocol ID: [20014](#) Millinger, Rachel

Cycle: 1

**Comments**

Get Protocol
Show All Comments
Submit to IRB

Comment 1

Select Section : Personnel Information

Please include research experience information for the Administrative Contact

**Response Necessary for Approval**
 **Suggestion Not Necessary for Approval**

Response :

Save
Clear

- When changes have been made in the protocol and all comments have been given a response, click “Submit to IRB” to submit comments. The Protocol Event status will then change to “Responses Sent (Cycle 1)”.

|                       |               |                          |  |                   |            |
|-----------------------|---------------|--------------------------|--|-------------------|------------|
| <a href="#">20024</a> | Fink, Melissa | African-American Studies | <a href="#">Responses Sent (Cycle 1)</a> | Bio #3 Full Board | 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:** Stamped attachments from the IRB as well as the approval letter will be accessed here.

| Event History |            |                  |                                  |                                 |
|---------------|------------|------------------|----------------------------------|---------------------------------|
|               | Date       | Status           | View Attachments                 | Letters                         |
|               | 08/08/2010 | PROTOCOL CREATED |                                  |                                 |
|               | 08/11/2010 | PREAPPROVAL      |                                  |                                 |
|               | 08/14/2010 | SUBMITTED        | <a href="#">View Attachments</a> |                                 |
|               | 08/19/2010 | PANEL ASSIGNED   |                                  |                                 |
|               | 09/01/2010 | APPROVED         | <a href="#">View Attachments</a> | <a href="#">Approval Letter</a> |

| Email History |   |
|---------------|---|
| Email Date    | Email Type  |
| 09/01/2010    | <a href="#">IRB Protocol Approved: 10-08-511, Millinger, Rachel</a>           |
| 08/19/2010    | <a href="#">IRB Protocol Assign to Panel: 10-08-511, Millinger, Rachel</a>    |
| 08/14/2010    | <a href="#">IRB Protocol has been submitted: 10-08-511, Millinger, Rachel</a> |

- **Event History/Status-**
  - **Protocol Created:** Date the protocol was created in the system. This status could also say “Protocol Cloned” indicating the date the protocol was cloned from another protocol in the system.
  - **Preapproval:** Date the protocol was pre-reviewed by the Department Chair in the system. **NOTE:** This is not the date the protocol was assigned for review, but rather the day it was returned.
  - **Submitted:** Date the protocol was submitted to the IRB. **NOTE:** This status is a link to view or print the protocol as it existed at the time of submission.
  - **Panel Assigned:** Date the protocol was sent from the Administrative Secretary of the IRB to the IRB Analyst.
  - **Approved:** Date the protocol was approved by the IRB. **NOTE:** This status is a link to view or print the protocol as it existed at the time of approval (after contingencies were addressed, etc).
- **Event History/View Attachments-**
  - Links to view and/or print attachments are in this column. Attachments are related to the corresponding status. Attachments with the submitted protocol are the documents that were uploaded for the IRB to review. Attachments with the approved protocol are the documents the IRB has approved, stamped and uploaded for the study team’s use.
- **Event History/Letters-**
  - Links to view and/or print are in this column. This is the official IRB approval letter. **NOTE:** Approval letters are now generated for subsequent forms on an approved protocol as well (i.e., Amendment, Continuing Review, etc.).
- **Email History/Email Type-** The links in this section will allow the user to view or print the corresponding emails that have occurred from the system to the PI/Administrative Contact regarding the protocol.

## Creating Other Forms

After a protocol has been approved, subsequent forms can be created from the “approved protocols” section of the dashboard or by selecting “approved protocols” from the left navigation investigator drop down menu.

The screenshot shows a table titled "Approved Protocols" with the following data:

| Protocol ID           | Principal Investigator | Department Name     | Initial Approval Date | Last Approval Date | Expiration Date | Status/Comments | Protocol Type |
|-----------------------|------------------------|---------------------|-----------------------|--------------------|-----------------|-----------------|---------------|
| <a href="#">20014</a> | Millinger, Rachel      | Research Compliance | 08/27/2010            | 08/27/2010         | 07/31/2011      | APPROVED        | NEW           |

A red arrow points from the "20014" link to a pop-up window titled "Approved Protocol Decision". The window contains the following text and options:

Approved Protocol Decision

Please select any one of the following:

- Open in View Mode
- Protocol Details
- Start Amendment
- Start Continuing Review
- Start Final Report Form
- Start Report Form
- Start Serious Adverse Event Form

Buttons: OK, Close

1. Click the Protocol ID number link of an approved protocol.
2. The available subsequent forms or post approval actions will appear on the “Approved Protocol Decision” pop-up menu.
3. Select the desired form to begin. Once selected, the new form will move to the corresponding section of the dashboard under “In Preparation/Submitted”.

The screenshot shows a table titled "AMENDMENT" with the following data:

| Protocol ID           | Principal Investigator | Department Name     | Protocol Event                       | Panel           | Meeting Date |
|-----------------------|------------------------|---------------------|--------------------------------------|-----------------|--------------|
| <a href="#">20008</a> | Millinger, Rachel      | Research Compliance | <a href="#">Yet to Submit to IRB</a> | Sandbox Panel 2 |              |

**NOTE:** “Open in View Mode” and “Protocol Details” will always be visible for the protocol. Multiple Serious Adverse Event and Report Forms may be created at any time. However, only one form can be active at a time for Amendments, Continuing Review, and the Final Report Form.

4. Subsequent forms are processed in the same way as a new submission. However, subsequent forms do not require Department Chair signature and can be submitted directly to the IRB after completion.

## Integrated Forms

Several forms no longer exist as separate word documents because they were integrated into the system as form content. This information can now be given as an answer within the form instead of as a separate document to be submitted to the IRB.

The following forms have been integrated:

- Request for Expedited Review Form
- HIPAA De-Identification Certification Form (see example below)
- Waiver or Alteration of HIPAA Authorization Form
- Request for waiver or alteration of Informed Consent or Written Consent

### HIPAA

Studies that receive or create protected health information (PHI) are subject to HIPAA regulations. PHI is health information with one or more personal identifiers. For more information see: <http://www.hhs.gov/ocr/hipaa/> or the [SLU HIPAA Tip Sheet](#).

**1. Will health information be received or collected?**

- No health information. HIPAA does not apply.
- Yes (continue to question 2).

**2. Which personal identifiers will be received or collected?**

- No identifiers. I certify that no identifiers from the list below will be received or collected and linked to health information. HIPAA does not apply (skip remainder of page).
- Names
- Social Security numbers

The HIPAA De-Identification Certification is now indicated by checking a box.

Note: \* denotes mandatory field.

**Informed Consent**
Save Cancel

Title \*

Consent Type \* Waiver of Consent

Address the following four points. A Yes/No response is not adequate.

- The research involves no more than minimal risk to the subjects.
- The waiver will not adversely affect the rights and welfare of the subjects.
- The research could not practicably be carried out without the waiver.
- Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

The Informed Consent Waiver Request Form is now a selection of questions on the Informed Consent page of the form. There is no need to upload the old paper form to the system.

## Glossary of Terms

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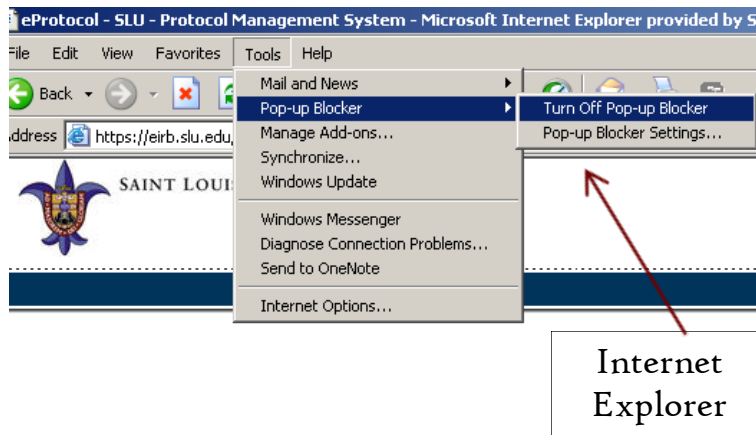
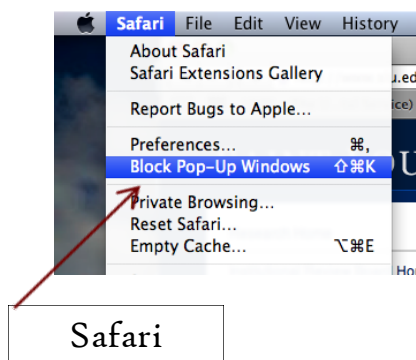
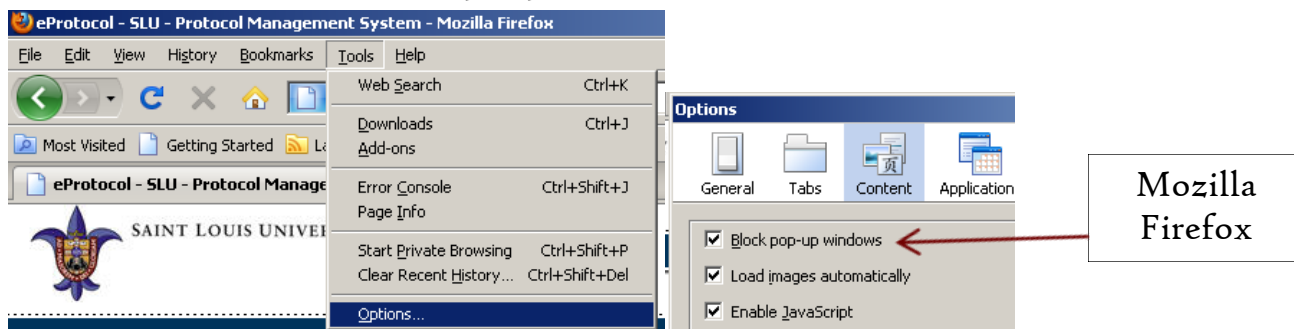
- **Protocol Events:**
  - **Pre-Review Required**– The protocol has not yet been approved/“signed” by the Department Chair/Advisor (or official proxy), is open for editing by the PI or Administrative Contact, and has not been submitted to the IRB.
  - **Submitted for Pre-Review**– The protocol has been submitted to the selected Department Chair/Advisor (or the acting proxy) and the Scientific/PPC Reviewer (if applicable) for electronic signature and approval.
  - **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.
  - **Yet to Submit to IRB**– The new protocol is open for editing by the PI or Administrative Contact, has been approved/“signed” by the Department Chair/Advisor or Scientific/PPC Reviewer, and has not been submitted to the IRB.
  - **Submitted to IRB**– The protocol has been submitted to the IRB and is locked for editing by the PI or Administrative Contact (view rights only).
  - **Comments Received (Cycle #)**– The IRB has returned a submission with comments or contingencies to be addressed by the PI. The comments page replaces the paper contingency letter. The cycle number will increase with each additional round of comment and response.
  - **Responses Sent (Cycle #)**– The PI has responded to the IRB’s comments and made edits and corrections in the protocol form and/or supplemental materials. The protocol is locked for editing and only be opened in view mode. The cycle number will increase with each additional round of comment and response.
- **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 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 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?!?!

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 on the IRB website, and by live support.

### Live support:

IRB Office:

(314) 977-7744

irb@slu.edu

### IRB website:

<http://www.slu.edu/x24634.xml>