SLU eIRB– Investigator Guide

Saint Louis University

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eIRB Investigator Submitter Guide

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Institutional Review Board

June 2011

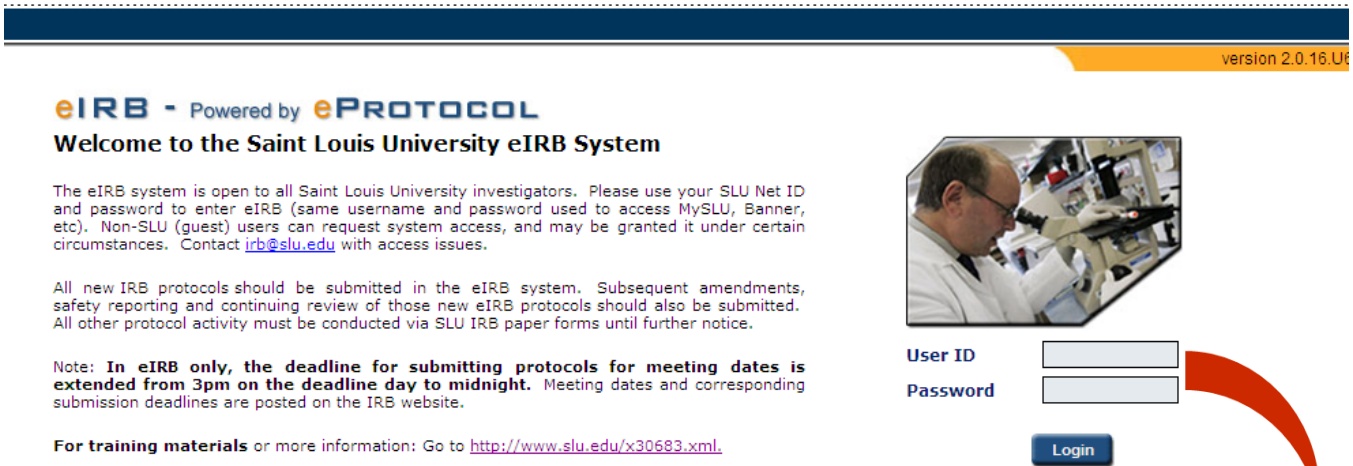
eIRB - Powered by ePROTOCOL

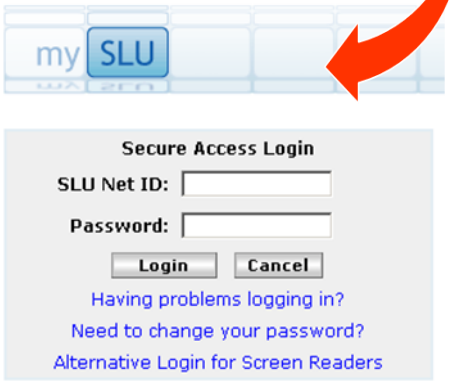
http://eirb.slu.edu

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?





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.

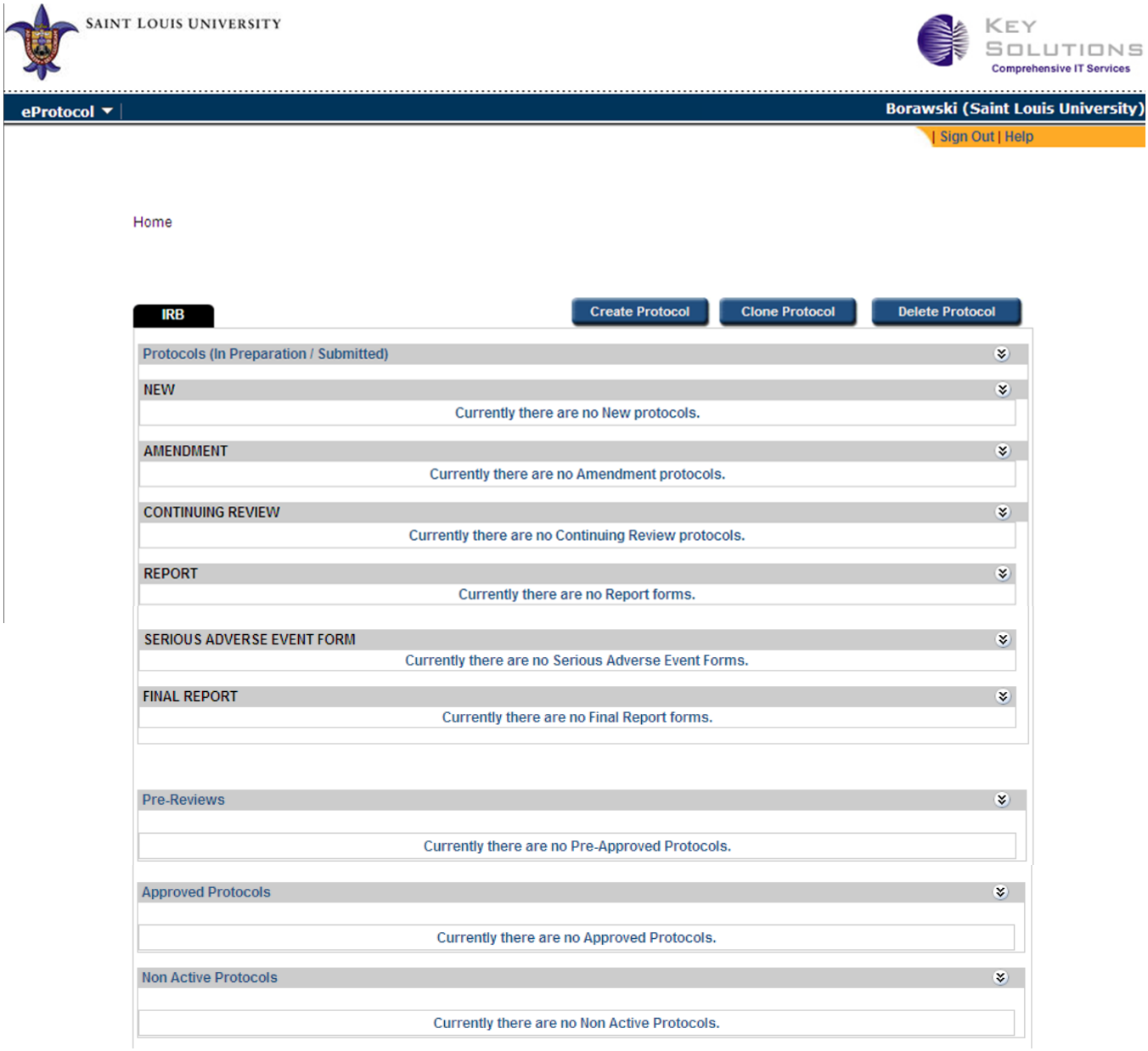
User ID = SLU Net ID: lastname@slu.edu

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.
- **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) or call the main office (314-977-7744).

The Dashboard/Homepage



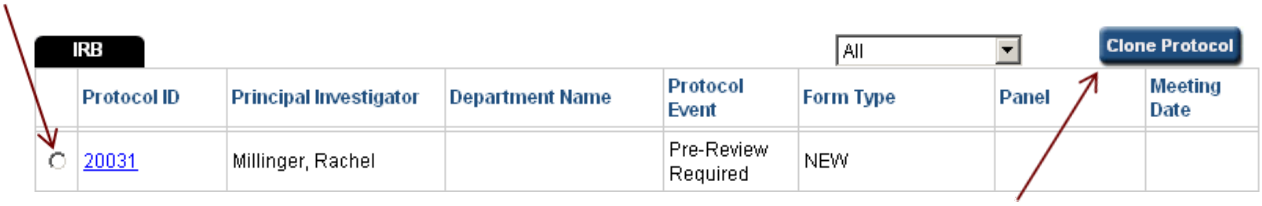
- The Investigator Dashboard or Homepage is a catalog of protocols:
  1) **In Preparation/Submitted**– Forms separated by type (e.g., New, Amendment, Continuing Review, etc.) that have not yet been submitted to the IRB for review or have been submitted to the IRB but have not yet been approved.
  2) **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: 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

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.



  - **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.

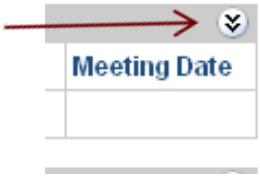
Dashboard/Homepage Terms

- **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.



- 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.

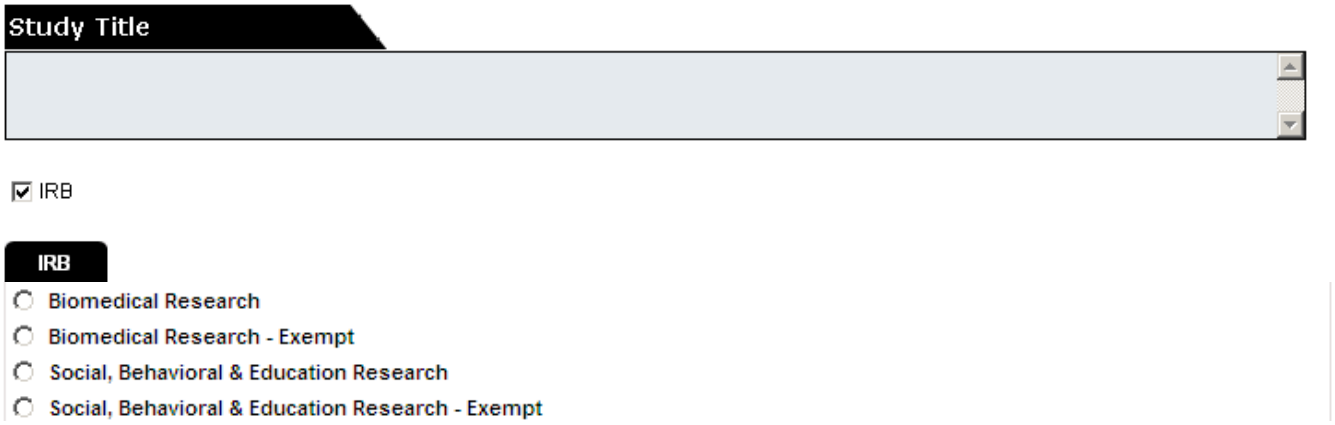
Creating a New Protocol

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

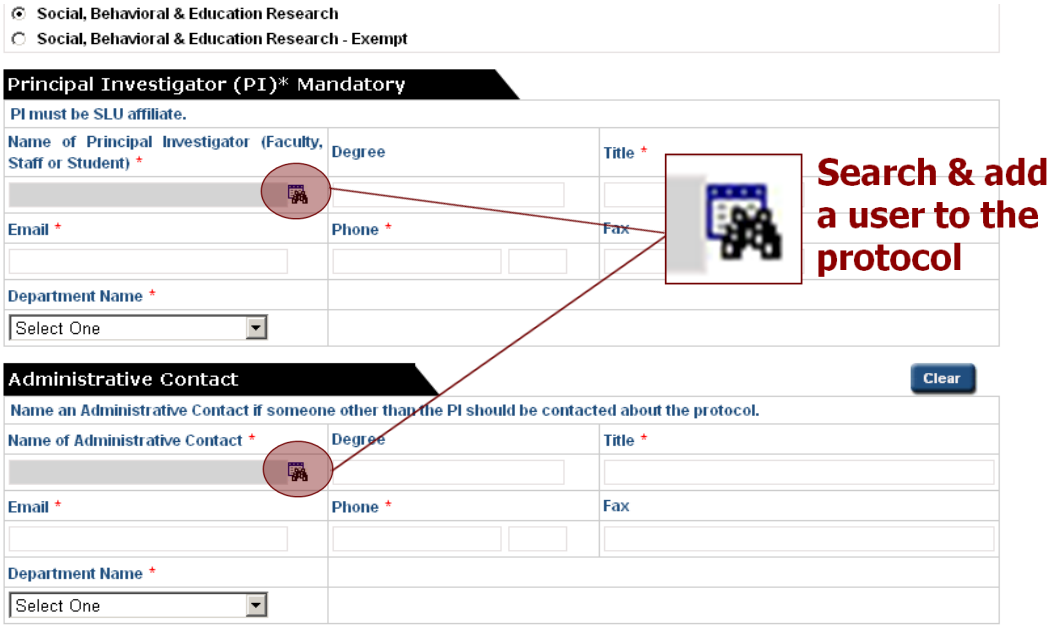
2. Enter the title of your study.

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.

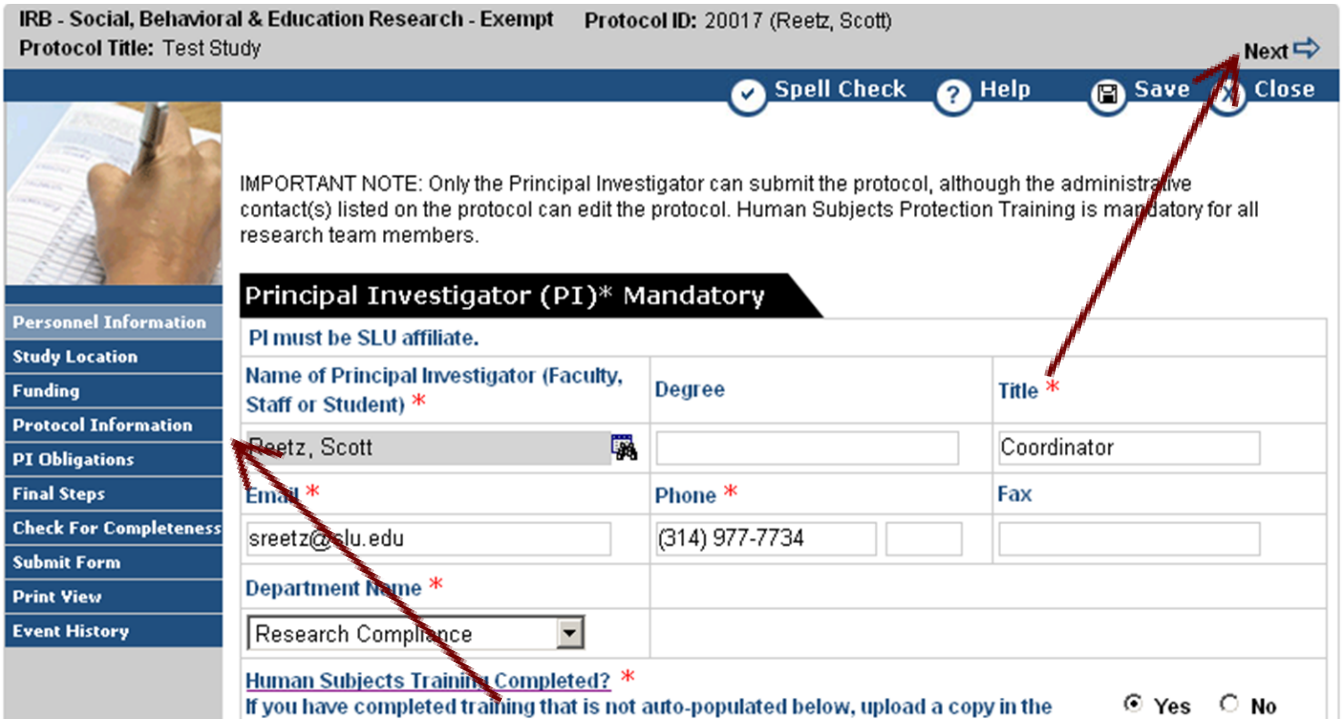
   NOTE: Researchers may not make an independent determination of whether a research study is exempt. Exempt does not mean that your research does not need IRB review. All exempt studies are initially reviewed by the IRB. Only the IRB can determine whether or not a study qualifies as exempt.



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.

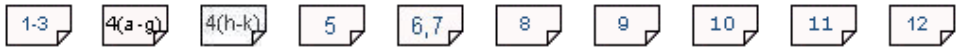


Completing the Form



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

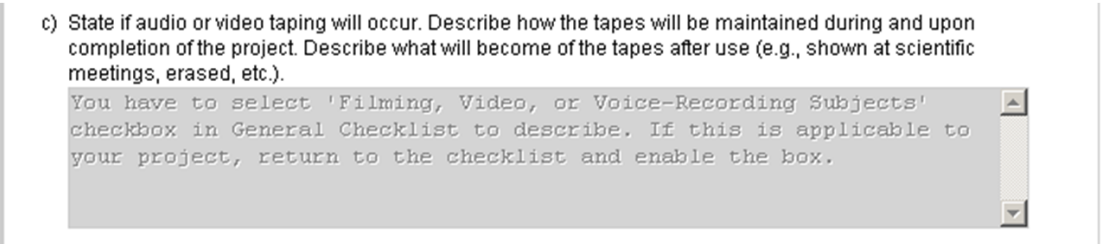
- Sections of the Form:
  - **Personnel Information**– Comparable to section A of the full paper form– use this section to add all the members of the research team based on their individual roles. See page 14 for more details on team member roles. NOTE: More than one Administrative Contact, Key Personnel (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.

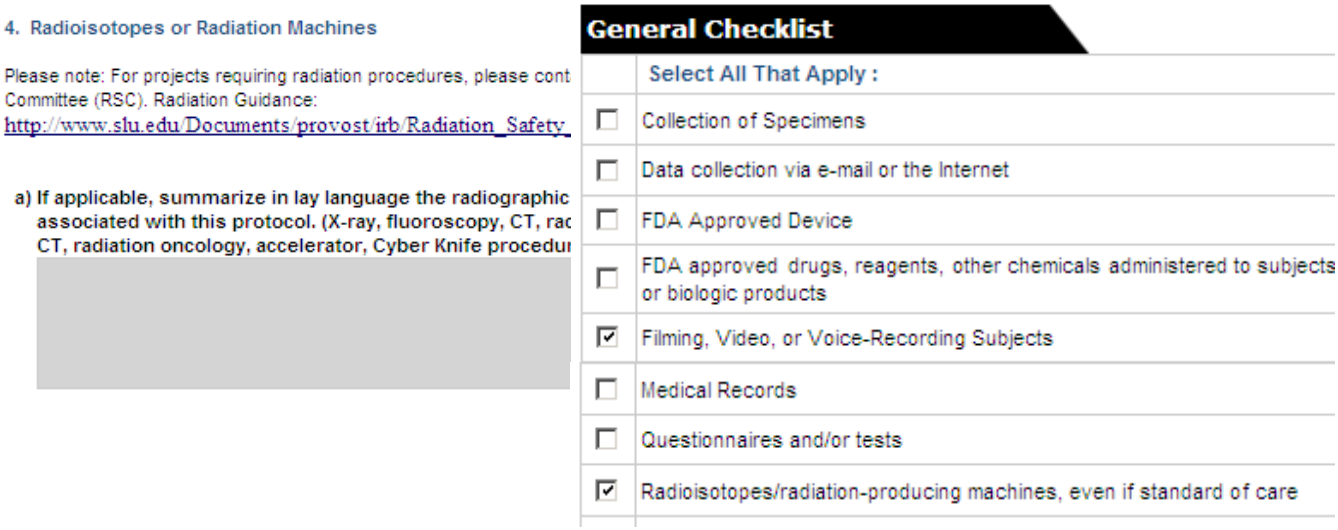


  - **PI Obligations**– The signature page where the PI will answer two questions regarding Conflicts of Interest and provide an electronic signature and assurance. NOTE: Only the PI can answer these questions and submit the protocol.
  - **Final Steps**– This page describes the final steps needed before 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

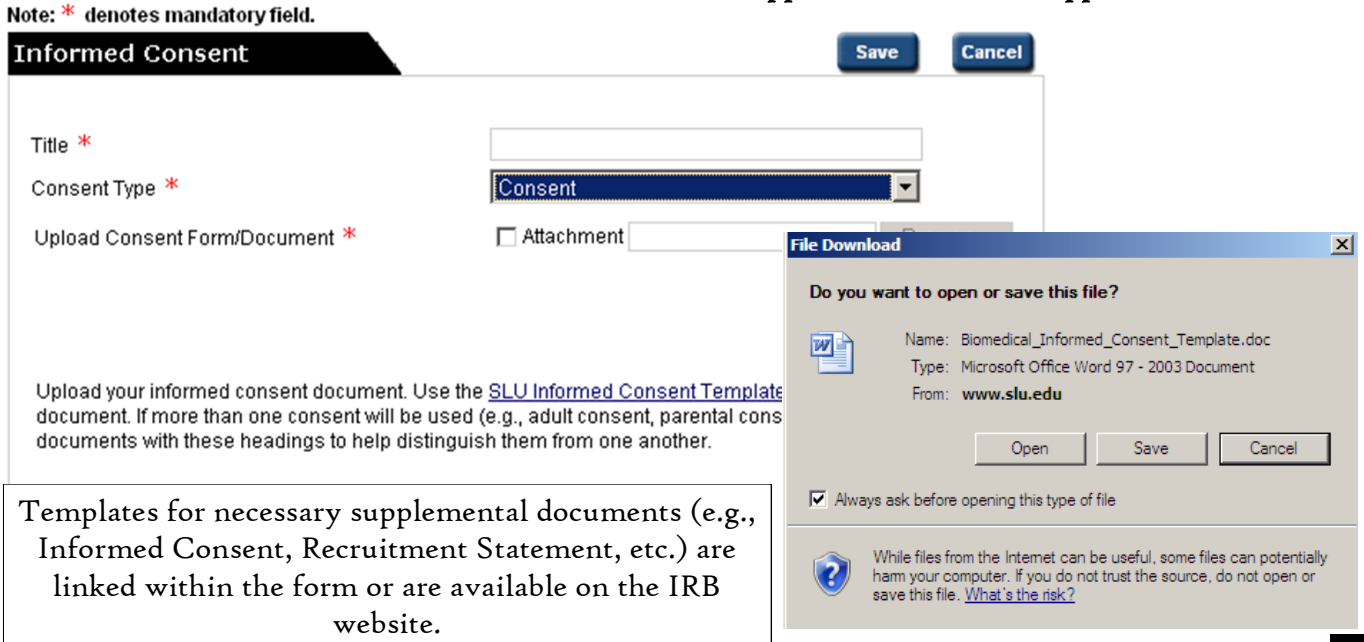
Some questions and sections of the form are inactive and cannot be answered unless activated in another section of the application (usually a checklist at the beginning of the form).





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.**



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:

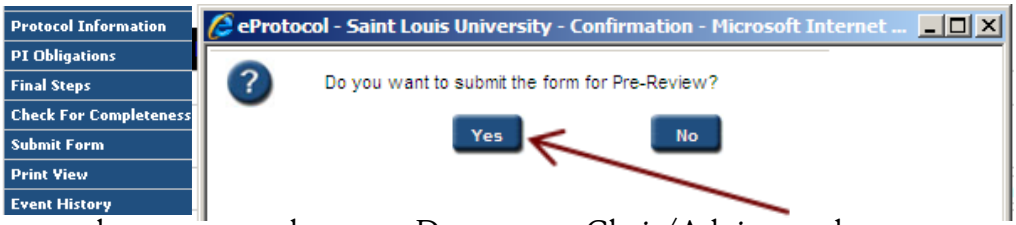
- A Scientific/PPC Review is needed for all investigator initiated protocols. Pharmaceutical sponsored trials and Biomedical Exempt protocols are **NOT** required to undergo this review.
- At least one scientific review is required. **NOTE:** The reviewer cannot be a member of the research team or the 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:

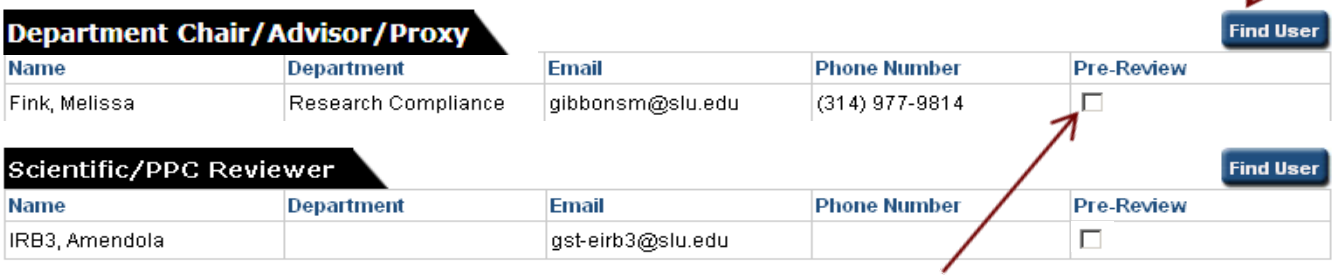
- The Department Chair/Advisor review (signature) is required for all protocols submitted to the IRB.
- If the Department Chair/Advisor is unavailable to review the protocol or if an official proxy has been established for the department, the IRB will likely accept that review. Please call the IRB office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



- 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

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 Dashboard will change to say, "Comments Received (Cycle 1)".

20031	Fink, Melissa	Anesthesiology	Comments Received (Cycle 1)

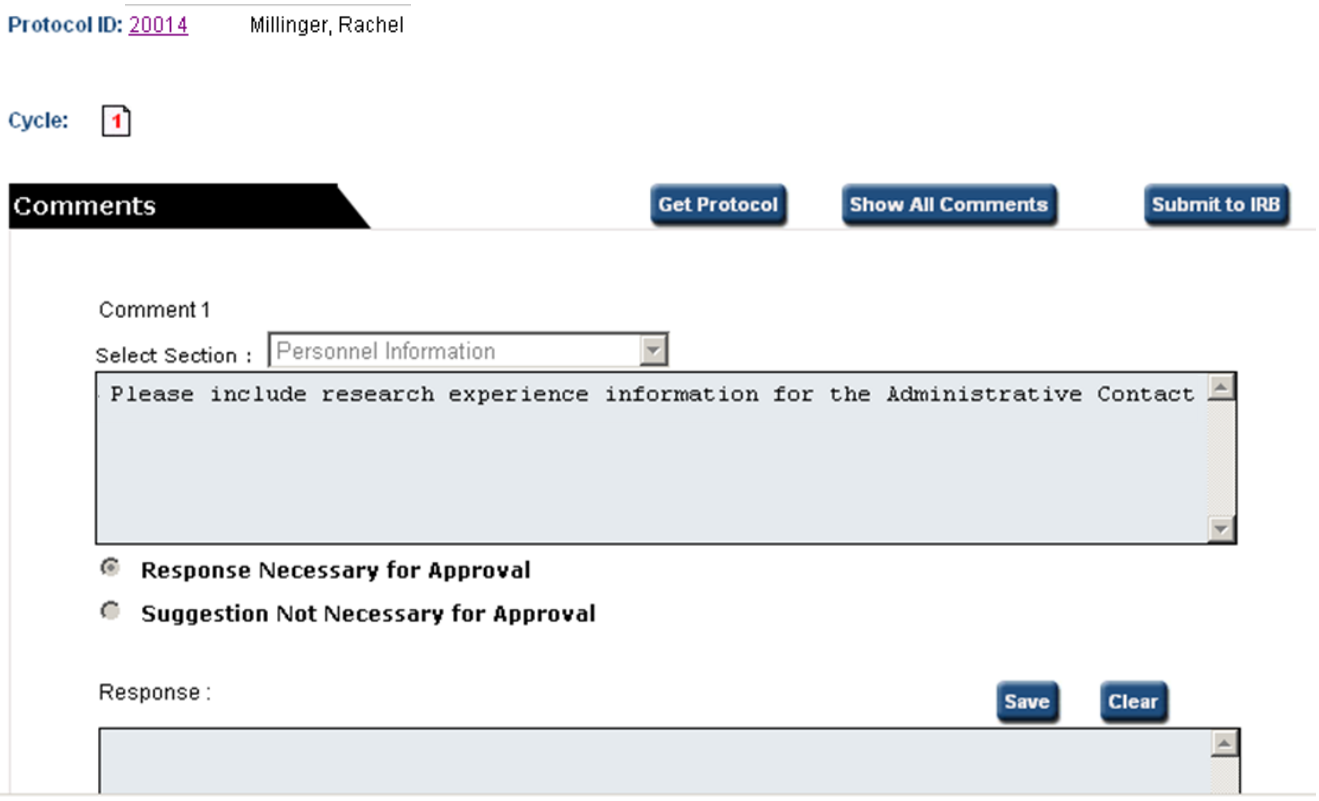
2. Click on the Protocol Event Link to bring up the comments/contingencies page.

3. Review the comments. Clicking "Show All Comments" will bring up a printable list of comments.

4. Comments should be addressed within the form by clicking "Get Protocol" and making the required changes.

5. 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.

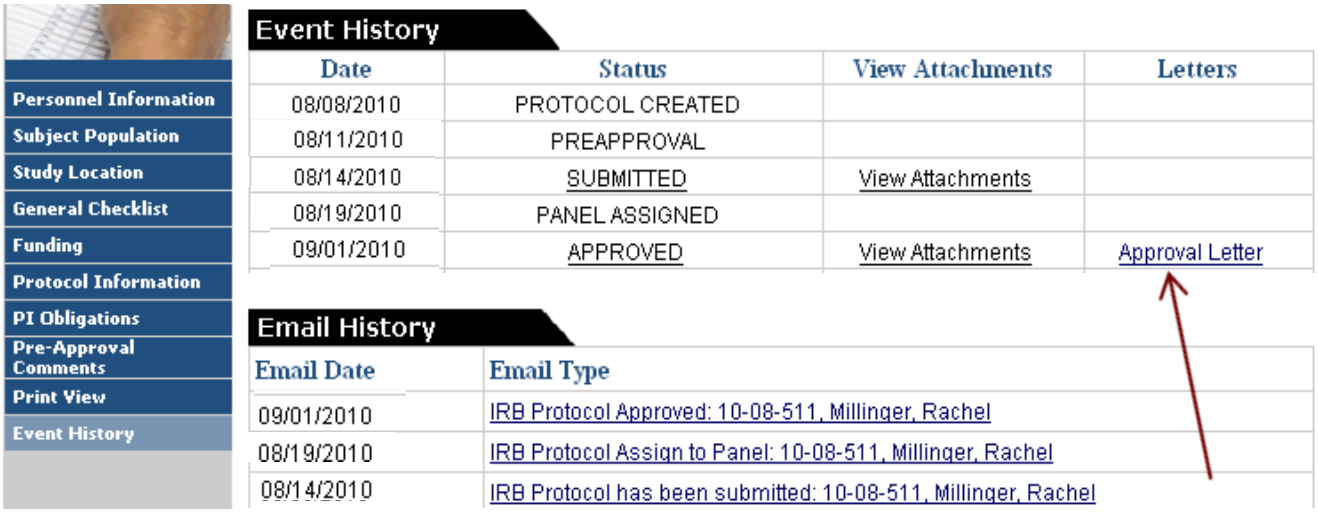


6. When changes have been made in the protocol and all comments have been given a response, click "Submit to IRB" to submit comments. The Protocol Event status will then change to "Responses Sent (Cycle 1)".

20024	Fink, Melissa	African-American Studies	Responses Sent (Cycle 1)	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.

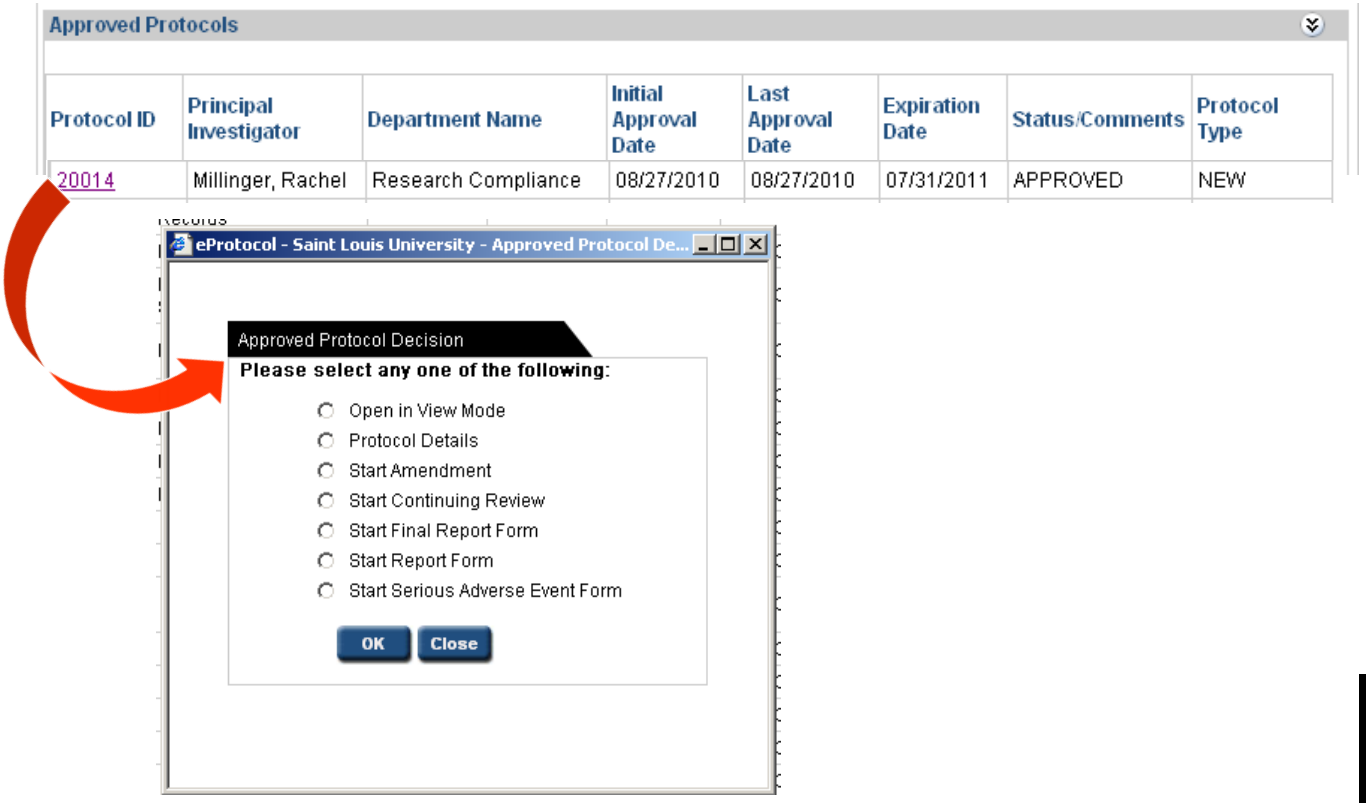


- Event History/Status–
  - **Protocol Created:** Date the protocol was created in the system. This status could also say "Protocol Cloned" indicating the date the protocol was cloned from another protocol in the system.
  - **Preapproval:** Date the protocol was pre-reviewed by the Department Chair 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

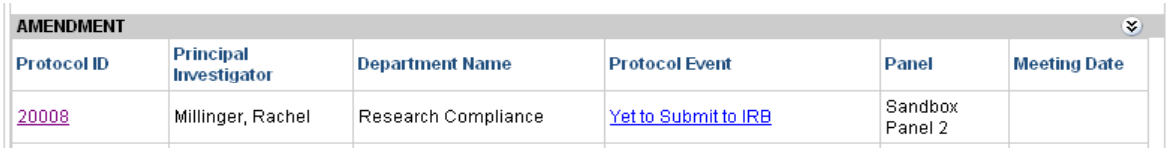
After a protocol has been approved, subsequent forms can be created from the "approved protocols" section of the dashboard or by selecting "approved protocols" from the left navigation investigator drop down menu.



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".



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.

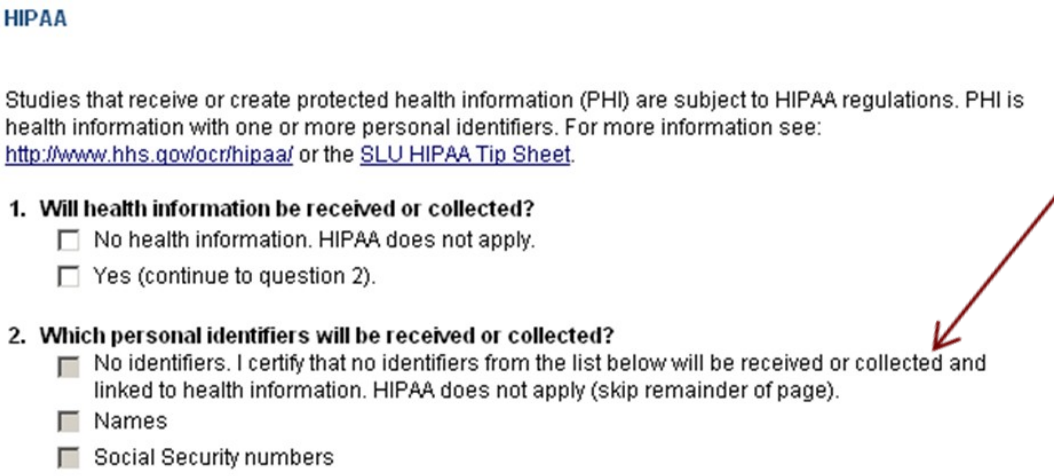
4. Subsequent forms are processed in the same way as a new submission. However, subsequent forms do not require Department Chair signature and can be submitted directly to the IRB after completion.

Integrated Forms

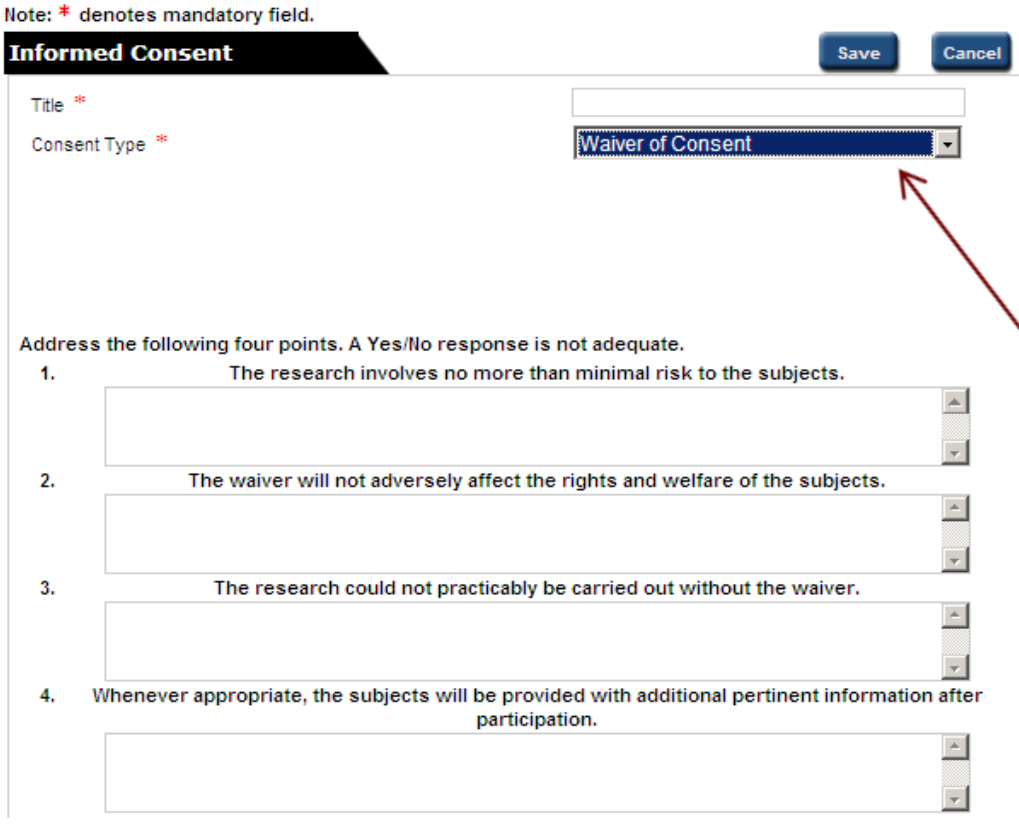
Several forms no longer exist as separate word documents because they were integrated into the system as form content. This information can now be given as an answer within the form instead of as a separate document to be submitted to the IRB.

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



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



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

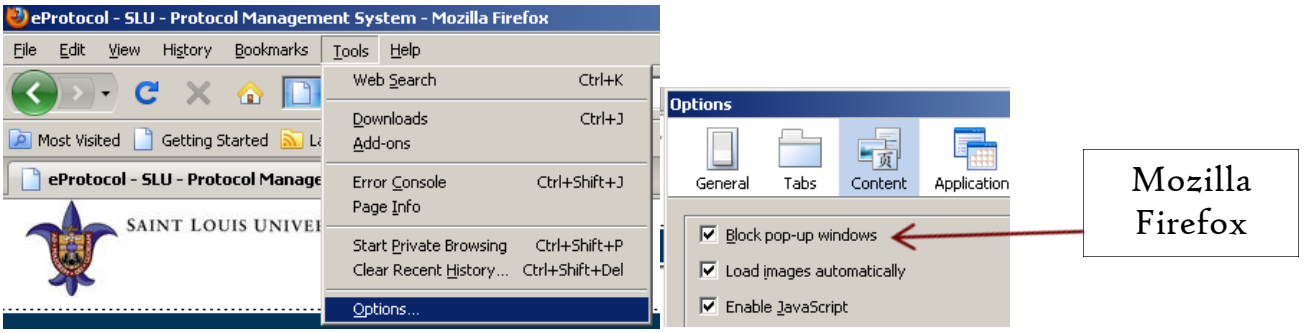
- Protocol Events:
  - **Pre-Review Required**– The protocol has not yet been approved/"signed" by the Department Chair/Advisor (or official proxy), is open for editing by the PI or Administrative Contact, and has not been submitted to the IRB.
  - **Submitted for Pre-Review**– The protocol has been 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.

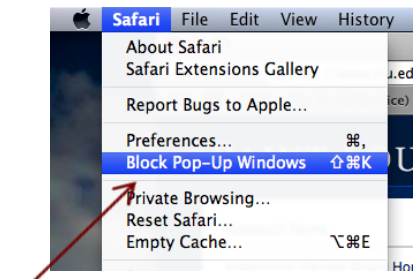
    NOTE: Biomedical protocols should list the officially named Department Chair in the Personnel Information section of the protocol. If a proxy will sign the protocol in lieu of the officially named Chair, that user will be named by the PI when the review is assigned.

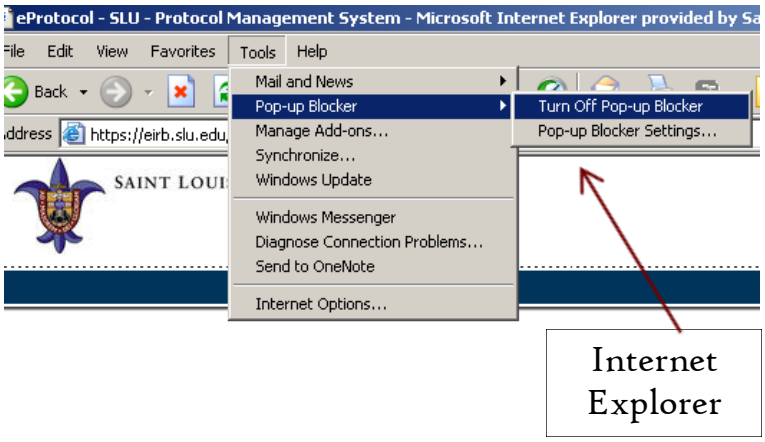
Disabling Pop-Up Blocker

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.

<u>Live support:</u>
IRB Office:
(314) 977-7744
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