

The SLU eIRB tip of the month

As you may know, education on the use of human subjects in research is **mandatory** at Saint Louis University. All faculty, staff, students, and collaborating researchers who are involved in the use of human subjects in research must complete the course of instruction offered by the Collaborative Institutional Review Board Training Initiative (CITI) Human Subjects Training at <http://citiprogram.org> or provide documentation of having completed a comparable human subjects research training course. More specific information on how to complete the training and what is required can be found on the Training and Education tab of the IRB website. In this month's tip, we'll highlight the eIRB system functionality regarding this mandatory training, including a few tips for ensuring an accurate connection between training records and 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](tel:3149777744)

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1. The IRB’s records regarding human subjects training are linked to the eIRB system. Training information should appear at the bottom of the personnel entry for each individual listed on the protocol. See below:

Save
Cancel

Administrative Contact

Name an Administrative Contact if someone in addition to the PI should be contacted about the protocol.

Name of Administrative Contact *	Degree	Title*
IRB3, Guest3		Guest
Email*	Phone*	Fax
gst-eirb3@slu.edu		
Department Name*		
Select One		

Is this individual also a member of the research team? * Yes No

Human Subjects Training Completed? * Yes No

If you have completed training that is not auto-populated below, upload a copy in the Attachments section.

Research Experience *

Research Team Member Duties Picklist *

1.	<input type="checkbox"/> Recruitment	2.	<input type="checkbox"/> Obtains consent
3.	<input type="checkbox"/> Determine Subject Eligibility for Accrual	4a.	<input type="checkbox"/> Subject Physical Examinations
4b.	<input type="checkbox"/> Follow-up Visits including physical assessments	5.	<input type="checkbox"/> Perform study procedures or Specimen Collection
6a.	<input type="checkbox"/> Administer and/or Dispense Study Drugs, Biologics or Devices (must be licensed)	6b.	<input type="checkbox"/> Receive, Store, Manipulate or Account for Study Drugs, Biologics or Devices
7.	<input type="checkbox"/> Subject Randomization or Registry	8.	<input type="checkbox"/> Collection of Subject Data
9.	<input type="checkbox"/> Report Data (CRFs, e-CRFs, Spreadsheets)	10.	<input type="checkbox"/> Data Analysis
11a.	<input type="checkbox"/> Review Adverse Events	11b.	<input type="checkbox"/> Treat and Classify Adverse Events
12.	<input type="checkbox"/> Other (Please insert explanation below.)		

UserID	CourseCompletionDate	Course
gst-eirb3	11-24-2010	CITI Social/Behavioral Research Basic Training
gst-eirb3	02-14-2011	CITI Biomedical Research Basic Training

CourseCompletionDate	Course
11-24-2010	CITI Social/Behavioral Research Basic Training
02-14-2011	CITI Biomedical Research Basic Training

2. Individuals who have not taken a CITI course, who have not affiliated their CITI account with Saint Louis University, or for any other reason have not provided proof of training to the IRB office (at the time they are added to the protocol) will not see a linked training record. See below:

Note: * denotes mandatory field.

Administrative Contact

Name an Administrative Contact if someone in addition to the PI should be contacted about the protocol.

Name of Administrative Contact *	Degree	Title*
IRB2, Guest2	<input type="text"/>	Guest
Email*	Phone*	Fax
gst-eirb2@slu.edu	<input type="text"/> <input type="text"/>	<input type="text"/>
Department Name*		
Select One ▼		

Is this individual also a member of the research team? * Yes No

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

Research Experience *

Research Team Member Duties Picklist *

1.	<input type="checkbox"/> Recruitment	2.	<input type="checkbox"/> Obtains consent
3.	<input type="checkbox"/> Determine Subject Eligibility for Accrual	4a.	<input type="checkbox"/> Subject Physical Examinations
4b.	<input type="checkbox"/> Follow-up Visits including physical assessments	5.	<input type="checkbox"/> Perform study procedures or Specimen Collection
6a.	<input type="checkbox"/> Administer and/or Dispense Study Drugs, Biologics or Devices (must be licensed)	6b.	<input type="checkbox"/> Receive, Store, Manipulate or Account for Study Drugs, Biologics or Devices
7.	<input type="checkbox"/> Subject Randomization or Registry	8.	<input type="checkbox"/> Collection of Subject Data
9.	<input type="checkbox"/> Report Data (CRFs, e-CRFs, Spreadsheets)	10.	<input type="checkbox"/> Data Analysis
11a.	<input type="checkbox"/> Review Adverse Events	11b.	<input type="checkbox"/> Treat and Classify Adverse Events
12.	<input type="checkbox"/> Other (Please insert explanation below.)		

No training data is available.

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Documentation of an approved educational program must be on file with the IRB office before research on human subjects may begin. Protocols submitted without documented approval will be returned to the research team before processing begins.

Individuals who have not taken a CITI course should follow the instructions on the IRB website, [here](#) in order to complete training. Individuals who have previously established a CITI account with another institution may add an affiliation with Saint Louis University to the already existing account. Individuals may also provide proof of comparable training directly to the IRB office to be linked with the eIRB record or may attach proof of training within the protocol. See below for more details:

If you have a completed training that did not auto-populate in the eIRB personnel record, a copy can be uploaded in the Attachments section. Upon receipt of the protocol, the IRB office will ensure the attached training is directly linked in the future. See below:

Note: * denotes mandatory field.

Attachments	
Document Type *	Select One
Attachment *	Select One
Document Name *	<ul style="list-style-type: none"> Archived Consent Materials (Office Use Only) Bibliography Committee Approvals Cooperating Institution's IRB Approval Data Collection Sheet Debriefing Script Device Information/Documentation Grant Proposal/Sub-Contract Human Subjects Training Certificate/Proof of Training

- Safety Information
- Scientific/PPC Review or Department Chair Re:IND Application Letter

If you believe your training record should show in eIRB and it is not, please call the office to resolve.

3. Individuals listed in the Non-SLU Collaborator section of the Personnel Information page do not have the linked training feature. A copy of training will need to be uploaded in the Attachments section for every Non-SLU Collaborator on every protocol.

Note: * denotes mandatory field.

Non - SLU Collaborator			
Name of Non-SLU Collaborator *	Degree (MD/PhD)	Title *	
<input type="text"/>	<input type="text"/>	<input type="text"/>	
Email *	Phone	Fax	
<input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/>	
Institution/ Company Affiliation *			
<input type="text"/>			
Human Subjects Training Completed? *	<input type="radio"/> Yes <input type="radio"/> No		
Please upload a copy of human subjects protection training in section #16 (Attachments). The IRB will likely accept comparable human subjects protection training other than CITI.			
If the research involves a non-SLU investigator/collaborator, it is the responsibility of the SLU PI to ensure that the non-SLU investigator/collaborator has obtained IRB approval from his/her institution (if applicable). A copy of the approval letter from the cooperative institution's IRB must be uploaded in the Attachment Section (#16).			
Research Experience *			
Research Team Member Duties Picklist*			
1.	<input type="checkbox"/> Recruitment	2.	<input type="checkbox"/> Obtains consent
3.	<input type="checkbox"/> Determine Subject Eligibility for Accrual	4a.	<input type="checkbox"/> Subject Physical Examinations
4b.	<input type="checkbox"/> Follow-up Visits including physical assessments	5.	<input type="checkbox"/> Perform study procedures or Specimen Collection
6a.	<input type="checkbox"/> Administer and/or Dispense Study Drugs, Biologics or Devices (must be licensed)	6b.	<input type="checkbox"/> Receive, Store, Manipulate or Account for Study Drugs, Biologics or Devices
7.	<input type="checkbox"/> Subject Randomization or Registry	8.	<input type="checkbox"/> Collection of Subject Data
9.	<input type="checkbox"/> Report Data (CRFs, e-CRFs, Spreadsheets)	10.	<input type="checkbox"/> Data Analysis
11a.	<input type="checkbox"/> Review Adverse Events	11b.	<input type="checkbox"/> Treat and Classify Adverse Events
12.	<input type="checkbox"/> Other (Please insert explanation below.)		


The following tips refer directly to your CITI account.

CITI Tip #1: Make sure you are selecting the correct course. The IRB office requires the first option listed on the CITI menu, “IRB Training”. You may be asked by other groups at the University to complete additional courses- this tip refers only to what is required by the IRB office. See below:

* To enable the software to present the appropriate course work for your needs, you will be asked a series of questions. Please read the questions carefully and provide the most appropriate answer.

Do you conduct research in any the following settings?
Choose all that apply

- Yes, Yes, I need to take IRB Training. I conduct research with live human beings, human tissue samples or with data derived from human beings
- Yes, I conduct research or teaching activities that utilizes live animal subjects or tissues derived from live animal subjects
- Yes, I want to complete or I am required to complete a course in the Responsible Conduct of Research (RCR). This course includes foundation textual materials, case studies and video scenarios. This does not include IRB training.
- I want to add the Good Clinical Practice Course to my courses
- Would you like to take the Conflict of Interest Course?

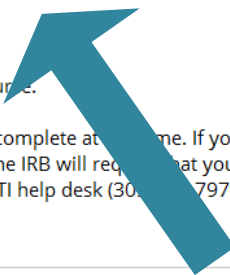


CITI Tip #2: For internal SLU researchers, the IRB requires proof of the Basic Course before the office will accept the refresher course. If you have never taken the CITI basic course, or a comparable alternative, you will need to select, “NO, I have NOT completed the Basic Course.” See below. Please note: The IRB office currently does not mandate a refresher course, but will at some point in the near future.

* In order to place you in the appropriate course we need to know if you have previously completed the Basic Course in the Protection of Human Research Subjects.
Choose one answer

- NO, I have NOT completed the Basic Course in the Protection of Human Research Subjects in the past. This is the first time using the CITI Program at this institution. I need to complete the Basic Course.
- Yes. I have completed the CITI Basic Course previously. It is time for me to complete the Refresher Course.

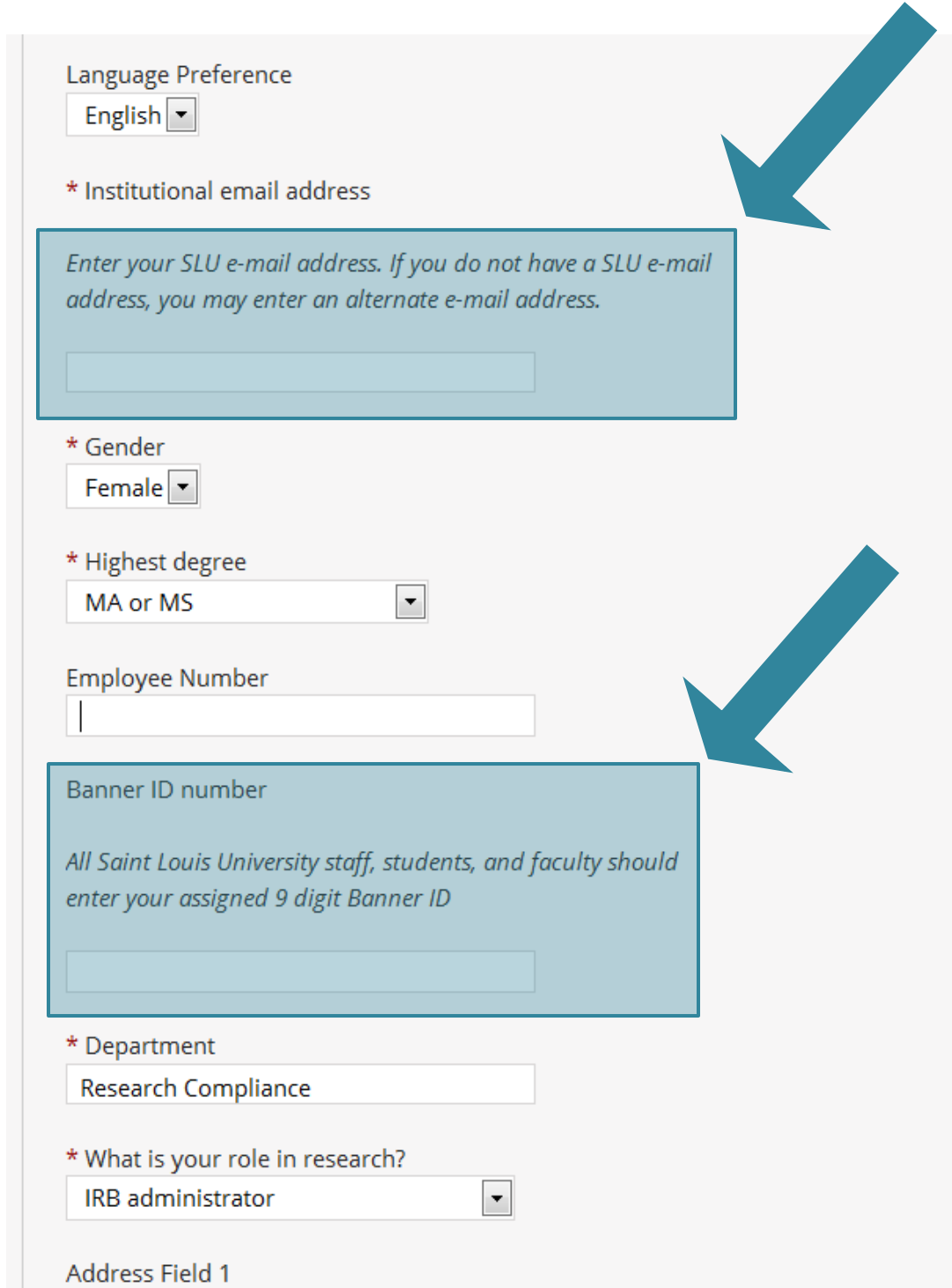
Note: Before you choose this Refresher Course make sure that this is the course that you are required to complete at your time. If you enroll in this course by mistake and complete the Refresher Course without previously completing the Basic Course , the IRB will require that you to come back to the the course site and complete the Basic Course. If you have questions, contact your IRB office or the CITI help desk (303.735.7970).



Next

Start Over

CITI Tip #3: For internal SLU researchers: To help ensure that your CITI training record links with the eIRB system properly, make sure to enter your Banner ID number and SLU email address. If you've already created a CITI account and didn't include this, the information can be added/updated at any time. See below:



Language Preference
English ▾

* Institutional email address

Enter your SLU e-mail address. If you do not have a SLU e-mail address, you may enter an alternate e-mail address.

* Gender
Female ▾

* Highest degree
MA or MS ▾

Employee Number
|

Banner ID number

All Saint Louis University staff, students, and faculty should enter your assigned 9 digit Banner ID

* Department
Research Compliance

* What is your role in research?
IRB administrator ▾

Address Field 1

*This tip was prepared in February 2014. 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.