**Saint Louis University Guidelines for Use of NCI Central IRB (CIRB)**

Saint Louis University (SLU) has partnered with the National Cancer Institute’s Central IRB (CIRB) for protocol review and oversight of NCI Cooperative Group clinical trials. To take part in the CIRB initiative, principal investigators must be approved by SLU and the CIRB. If you are interested in taking part, you may contact the SLU IRB office at 977-7744 or irb@slu.edu for more information.

In general, a NCI Cooperative Group clinical trial may be eligible for submission to CIRB if it meets the following criteria:

* Protocol has already been approved by CIRB
* Protocol is being submitted by an authorized PI
* Protocol does not involve prisoners

SLU will not allow submission to CIRB without prior authorization. To obtain the necessary approval, investigators must go through an administrative review process, described below. Note that this review is not an IRB review, but it does involve reviewing proposed research to ensure:

* the proposed research study is eligible for submission to CIRB;
* the study is in alignment with the University’s Catholic mission and any relevant policies;
* the research is being conducted at sites where appropriate research agreements are in place;
* investigators and research staff are appropriately qualified and resourced;
* the language in the consent documents meet institutional and contractual requirements;
* appropriate financial arrangements have been made; and
* University concerns, including radiation safety, biological safety and risk management, are being addressed.

**STEPS FOR SUBMITTING TO CIRB (**[**See CIRB Submission Quick Sheet**](https://www.slu.edu/research/faculty-resources/research-integrity-safety/institutional-review-board-irb/irb_assets/nci_cirb_submission_quick_sheet.docx)**)**

**Initial Submission Process**

**Step 1: Identify an eligible study; complete but do not submit CIRB Study-Specific Worksheet.**

Studies and related materials approved by the CIRB are made available to participants on the CIRB website. To gain access to the CIRB participant site, investigators should complete the [Contact Form](http://www.ncicirb.org/CIRB_Update_Person_Inst_Info.asp) and send it to the SLU IRB office at irb@slu.edu.

Research staff should download all current review materials linked to the research study, including the application, protocol, consent/assent forms, CIRB approval letter, SAEs, recruitment materials and other documents. These will need to be submitted to the SLU IRB Office for review (see Step 3).

Research staff should fill out the CIRB Study-Specific Worksheet for the study of interest, but should not yet submit it for CIRB review. At this Step, complete the form and print a PDF to submit to the SLU IRB office in step 3.

**Step 2: Investigator begins local processes necessary for all clinical trials at SLU.** To get approval for submission to CIRB, financial requirements, such as submission of financial agreements in eRS, must be met (for details, contact the Clinical Trials Office at 977-6335 or clinical-trials-office@slu.edu).

All investigators listed on the study must also have annual disclosures on file with the conflict of interest office and must have completed training in human subjects research protections.

**Step 3: Submit the NCI CIRB Submission Authorization Form (SLU form)**, along with required attachments, to the SLU IRB Office**.** This is currently done using the paper form, but materials can be submitted on paper or by e-mail to irb@slu.edu. The SLU IRB office facilitates the SLU administrative review process; **submission to CIRB cannot occur until the Submission Authorization Form is approved**.

Note that the following will be required for the SLU Administrative Review Process:

* **Completed NCI CIRB Submission Authorization Form (SLU form)**
* **Final draft of the CIRB Study-Specific Worksheet**, noted in Step 1, above.
* **CIRB study materials,** noted in Step 1, above.
* **Consent or Assent Documents to be used at SLU (with boilerplate language incorporated)**
	+ SLU investigators will be responsible for generating the SLU consents/assents by adding [required boilerplate language](https://www.slu.edu/research/faculty-resources/research-integrity-safety/institutional-review-board-irb/irb_assets/nci_cirb_slu_boilerplate_language.doc) into the sponsor consents.
* **HIPAA Documents**
	+ SLU investigators will be responsible for generating the HIPAA Authorization Form. Please use the standard SLU template HIPAA Authorization Form when preparing this document.

The SLU IRB office will route materials to other SLU offices as needed (Clinical Trials Office, General Counsel, Radiation Safety, Conflict of Interest, etc.) for review. However, **if investigators are aware that approvals will be necessary from other offices or committees, they are encouraged to work with these groups directly as soon as possible** to expedite processes. NOTE: investigators are responsible for completing the SSM Research Business Review (RBR) form. In urgent scenarios, RBR can run concurrently with SLU Administrative Review/CIRB review; under normal circumstances, the RBR process will commence once the CIRB approval letter has been received. Contact Marcy Young at marcy\_young@ssmhc.com with questions/concerns.

If issues arise during SLU Administrative Review, the PI or study contact will be contacted and revisions may be requested.

**Step 4: Submission to CIRB.** Once SLU authorization (the signed NCI CIRB Submission Authorization Form) is received, the investigator can proceed with submission of materials to CIRB. **PI’s must refer to Appendix B of the form for any required revisions to the Study-Specific Worksheet, including locally required additions to or deviation from CIRB-approved Boilerplate language.**

The CIRB website can be referenced for assistance in submitting materials (<https://www.ncicirb.org/>).

**Step 5: CIRB Review.** CIRB will contact the investigator/contact person directly with questions about the submission, and with determinations of approval or disapproval. SLU IRB is copied on the approval determination.

**Step 6: Do not commence research until all institutional approvals are in place.** Make sure that all institutional approvals, including hospital approvals, are in place prior to beginning the study.

**Post-Approval Submission Requirements**

The CIRB and Saint Louis University each have responsibilities for overseeing this research, thus there are reporting requirements to both organizations.

**SUBMISSIONS TO CIRB AFTER INITIAL APPROVAL:**

Investigators should submit subsequent protocol documents, events or activities directly to CIRB according to guidelines provided by CIRB. Submissions to CIRB include:

* Unanticipated Problems (may or may not also be an SAE)
* Continuing or Serious Noncompliance reports
* Closure Notifications
* Other submissions required by CIRB, such as locally developed recruitment materials

*SLU IRB must be notified prior to formally submitting in the CIRB system; email irb@slu.edu.*

**SUBMISSIONS TO SLU IRB AFTER INITIAL APPROVAL:**

To ensure appropriate institutional oversight of research activities, investigators should directly submit the following to the SLU IRB Office:

* Protocol Amendments that change local context, such as consent/assent/HIPAA Authorization changes or changes to study team members (via Change-in-Protocol Form)
* Annual progress reports (via annual submission of Continuing Review Form)
* SAEs, Unanticipated Problems, Protocol Violations\*
* Subject complaints\*
* Breaches of confidentiality\*
* Audit notifications\*
* Monitor reports\*

*\*Items should be submitted in accordance with definitions and submission requirements detailed in the SLU IRB* [*Requirements for Reporting Events Relating to Subjects/Subject Safety*](https://www.slu.edu/research/faculty-resources/research-integrity-safety/institutional-review-board-irb/irb_assets/guidelines_reportable_events.doc)*.*

Submit using SLU paper forms to the IRB Office or irb@slu.edu. SLU IRB will route information related to these reports to university officials as needed for review; however, investigators should also contact General Counsel and/or the SLU Privacy Officer when appropriate.

**Questions and Contacts**

Contact irb@slu.edu or call 977-7744 with questions about the CIRB process and SLU requirements.

Questions regarding CIRB submission and reporting requirements are best handled by contacting CIRB directly or by visiting <https://www.ncicirb.org/>.