**Saint Louis University Institutional Review Board**

**Quick Sheet for Submitting to NCI CIRB**

|  |
| --- |
|  |
| [ ]  | Verify that the protocol is eligible for submission to CIRB: [ ]  Active CIRB-approved protocol. [ ]  CIRB-approved/authorized PI. [ ]  Research will NOT involve prisoners. |
| [ ]  | Complete CIRB Study-Specific Worksheet & Download Study Materials for Submission to SLU\*: [ ]  Complete **but do not submit** Study-Specific Worksheet. Print/download final draft as PDF.  [ ]  Download protocol documents, including CIRB application, protocol, consent/assent documents,  CIRB approval letter, SAE reports and other pertinent study materials.*\*These materials will be submitted along with the* [*SLU NCI CIRB Submission Authorization Form*](https://www.slu.edu/research/faculty-resources/research-integrity-safety/institutional-review-board-irb/irb_assets/nci_cirb_application.doc) |
| [ ]  | Initiate/Satisfy Other Institutional Research Requirements: [ ]  Researchers have completed Annual COI Disclosure per SLU Policy. [ ]  Researchers have completed required human subjects protections (IRB) training. [ ]  Financial documents have been submitted in eRS. [ ]  Begin the RBR Form for SSM Protocols *(do after CIRB approval if not urgent)* |
| [ ]  | Submit the NCI CIRB Submission Authorization Form (SLU form) & necessary attachments for local administrative review and approval, including the locally-developed consent, assent, and HIPAA Authorization forms. *Indicate to IRB Staff if urgent*. |
| [ ]  | Once SLU Authorization is obtained, submit the CIRB Study-Specific Worksheet in the CIRB system, *making sure to incorporate local requests noted on Appendix B of the NCI CIRB Submission Authorization Form*.  |
| [ ]  | Provide the CIRB approval letter to SSM to complete RBR attachments, and ensure all other necessary SLU and hospital approvals are in place prior to commencing research. |
|  | Post-Approval Submissions |
| [ ]  | Submissions to CIRB:* 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. E-mail irb@slu.edu.* |
| [ ]  | Submissions to SLU IRB:* Protocol Amendments that change local context, such as consent/assent/HIPAA Authorization changes or changes to study team (Change-in-Protocol Form)
* Annual progress reports (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)*.*  |

Questions about the SLU NCI CIRB Process can go to 314-977-7744 or irb@slu.edu.

Questions about CIRB System and Requirements can go to <https://ncicirb.org/>.