**Saint Louis University**

**Post Approval Submission Requirements – Central/External IRB Use**

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| **Type of Submission** | **What to Submit** | | | | | |
| **If using an independent central IRB partner (WIRB & Affiliates, Advarra, Quorum)** | | **If using NCI CIRB** | | **If using StrokeNet IRB or an External IRB (non-partner IRB via an exception)** | |
| **To Central IRB** | **To SLU** | **To NCI-CIRB** | **To SLU** | **To Reviewing IRB** | **To SLU** |
| **Local Changes to SAF\* (personnel, payment, etc.).** | As required by central | Email SLU SAF with changes tracked prior to implementing; new signatures only needed if change in PI | As required by NCI-CIRB | Change-In-Protocol Form | As required by Reviewing IRB | Email SLU SAF with changes tracked prior to implementing; new signatures only needed if change in PI |
| **Changes to SLU HIPAA Authorization Form** | As required by central | Email revised Word version of HIPAA with changes tracked | As required by NCI-CIRB | Change-In-Protocol Form and revised HIPAA with changes tracked and clean copy | As required by Reviewing IRB | Email revised Word version of HIPAA with changes tracked |
| **Protocol Amendments (study-wide changes) or IB Changes** | Typically submitted by Sponsor unless using as local IRB | Nothing Required | As required by NCI-CIRB | Change-In-Protocol Form | Submit as required by Reviewing IRB unless sponsor submits on SLU’s behalf | Nothing Required |
| **Changes to consent materials/recruitment materials (study-wide, not local language)** | Typically submitted by Sponsor unless using as local IRB | Nothing Required | As required by NCI-CIRB | Change-In-Protocol Form and revised consents with changes tracked and clean copy | As required by Reviewing IRB | Nothing Required |
| **Changes to consent materials/recruitment materials impacting local language** | Submit as required by central unless sponsor submits on SLU’s behalf | Email tracked changes for review prior to central IRB; otherwise will review during/after Central | As required by NCI-CIRB | Change-In-Protocol Form and revised consents with changes tracked and clean copy | Submit as required by Reviewing IRB unless sponsor submits on SLU’s behalf | Email tracked changes for review prior to External IRB; otherwise will review during/after External |
| **Continuing Reviews** | Site progress reports or other form as required by central | Email copy of documents submitted to central IRB | As required by NCI-CIRB | Continuing Review Form | As required by Reviewing IRB | Email copy of documents submitted to Reviewing IRB |
| **Unanticipated Problem (Local UP that may or may not also be an SAE)** | Central IRB form as required by central IRB. | Email copy of documents submitted to central IRB | As required by NCI-CIRB | Change-In-Protocol/For Information form | As required by Reviewing IRB | Email copy of documents submitted to Reviewing IRB |
| **SAEs that are not UPs** | As required by central | Email [SLU SAE Form](https://www.slu.edu/research/faculty-resources/research-integrity-safety/institutional-review-board-irb/irb_assets/form_serious_adverse_event.doc) according to timelines described in [SLU Safety Reporting Guidelines](https://www.slu.edu/research/faculty-resources/research-integrity-safety/institutional-review-board-irb/irb_assets/guidelines_reportable_events.doc). | As required by NCI-CIRB | Email [SLU SAE Form](https://www.slu.edu/research/faculty-resources/research-integrity-safety/institutional-review-board-irb/irb_assets/form_serious_adverse_event.doc) according to timelines described in [SLU Safety Reporting Guidelines](https://www.slu.edu/research/faculty-resources/research-integrity-safety/institutional-review-board-irb/irb_assets/guidelines_reportable_events.doc). | As required by Reviewing IRB | Email [SLU SAE Form](https://www.slu.edu/research/faculty-resources/research-integrity-safety/institutional-review-board-irb/irb_assets/form_serious_adverse_event.doc) according to timelines described in [SLU Safety Reporting Guidelines](https://www.slu.edu/research/faculty-resources/research-integrity-safety/institutional-review-board-irb/irb_assets/guidelines_reportable_events.doc). |
| **Protocol violations that affect subject rights/safety or data integrity; consenting errors** | Central IRB form as required by central IRB. | Email copy of documents submitted to central IRB | As required by NCI-CIRB | Change-In-Protocol/For Information form | As required by Reviewing IRB | Email copy of documents submitted to Reviewing IRB |
| **SLU Site Monitor Reports** | As required by central | Email copy to [irb@slu.edu](mailto:irb@slu.edu) | As required by NCI-CIRB | Change-In-Protocol/For Information form | As required by Reviewing IRB | Email copy to [irb@slu.edu](mailto:irb@slu.edu) |
| **DSMB Reports** | Typically submitted by Sponsor unless using as local IRB | Nothing Required if recommends continuance | As required by NCI-CIRB | With continuing review reports | As required by Reviewing IRB | Nothing Required if recommends continuance |
| **Unresolved Subject Complaints, Data Security Incidents, Audit Notifications** | As required by central | Email [irb@slu.edu](mailto:irb@slu.edu) | As required by NCI-CIRB | Change-In-Protocol/For Information form | As required by Reviewing IRB | Email [irb@slu.edu](mailto:irb@slu.edu) |
| **Study Closures** | Central IRB form as required by central IRB. | Nothing required; courtesy email optional | As required by NCI-CIRB | Continuing Review/Closure Form | As required by Reviewing IRB | Email copy of documents submitted to Reviewing IRB |