Saint Louis University Institutional Review Board
Serious Adverse Event (SAE) Decision Tree

Did the event occur at SLU or a SLU affiliated site?

Yes

Is the event related or possibly related to participation in the research?

Yes

Is the event life threatening or did it result in death?

Yes

SAE Report Form. Use the paper form if the protocol is not yet in eIRB; otherwise, submit using the SAE Report Form in eIRB.

No

No

Event is not reportable to SLU IRB.

No

No

Event is not an SAE, but may still be an Unanticipated Problem (UP).
Please see UP Decision Tree

Yes

Event is an SAE.
Report to IRB within 7 days.

Did the event result in any of the following?

- Congenital anomaly or birth defect
- Significant disability or incapacity
- Inpatient hospitalization or the prolonging of existing hospitalization
- Any other important medical event that may jeopardize the subject and may require medical or surgical intervention to prevent one of the outcomes listed above

No

Yes

Event is an SAE.
Report to IRB within 7 days.

SAEs are to be reported on the SAE Report Form. Use the paper form if the protocol is not yet in eIRB; otherwise, submit using the SAE Report Form in eIRB.

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