Saint Louis University Institutional Review Board Protocol Violation (PV) 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?

No

Event is not reportable to SLU IRB.

Yes

Did the event place participants or others at a greater risk of harm (including physical, psychological, economic, or social harm) than if the protocol was followed as intended?

Yes

Did the event involve any of the following?

- An unintentional variation from the approved research protocol
- An error in the conduct of the study
- Failure to get IRB approval prior to implementation of a protocol deviation
- A consent violation

No

Event is not a reportable PV.

Yes

Event is a PV. Report to IRB within 7 days from the date the violation becomes known.

Did the variation involve a consent violation or the implementation of a protocol deviation without prior IRB approval?

Yes

Event is a PV. Report to IRB within 7 days from the date the violation becomes known.

No

Event is not a reportable PV.

PVs are to be reported on the Report Form in eIRB. Use the paper form if the protocol is not yet in eIRB. PVs that result in SAEs are to be reported on the SAE form within 3 days of the event or the date when the SLU site was notified of the event. If the PV results in the death of a subject, notify the IRB immediately (via phone or email).

Version Date: 8/2013