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

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 **reportable consent violation**

No

Event is not a reportable PV.

Yes

Did the variation involve a **reportable 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 should be reported on the Report Form in eIRB. Submit the [Change-in-Protocol/For Information Only form](#) if the study is not in eIRB.

PVs that result in SAEs are to be reported in accordance with SAE required timelines.

If the PV results in the death of a subject, notify the IRB immediately at 977-7744 or [irb@slu.edu](mailto:irb@slu.edu).

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