Saint Louis University Institutional Review Board

Unanticipated Problem (UP) Decision Tree

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

Yes →

Did the event occur at a SLU site or SLU-affiliated site (including any site under the jurisdiction of the SLU IRB)?

Yes →

Did the event involve a medical device and relate to the rights, safety, or welfare of a subject?

No →

Did the event do both of the following?

- Suggest that the research places subjects or others at greater risk of harm (physical, psychological, economic, or social) than previously known or recognized
- Become inconsistent with or exceed the nature, severity, or frequency described in the protocol, consent form, investigator’s brochure, or supporting documents, or given the subject population

Yes →

Event is a UP. Report to IRB within 7 days.

No →

Event is not a UP. No need to report.

Yes →

Is this a multi-center study, and the event occurred at an external site?

Yes →

Report to IRB within 7 days of notification by sponsor.

No →

Event is not a UP. No need to report.

Event is not a UP. No need to report.

UPs should be submitted on the Report Form in eIRB (Change in Protocol (CIP) form for paper protocols). UPs that are also SAEs (See SAE Decision Tree) should be submitted on the SAE Form. Any changes to the protocol/materials should be done via an Amendment (CIP for paper protocols).

Submit internal and sponsor-reported UPs to the SLU IRB within 7 calendar days of the event or date the SLU site was notified of the event. Note: some sponsor amendments that include changes to risks, inclusion/exclusion criteria and/or study design are often a result of UPs, and as such should be submitted to the IRB promptly, within 15 business days of receipt.

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