Saint Louis University Institutional Review Board

Unanticipated Problem (UP) Decision Tree

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

No → Event is not a UP. No need to report.

Yes →

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

No → If it occurred at an External site, did the event do one of the following?

- Require an immediate change to the protocol to address the risk raised by the event
- A sponsor, monitor, or external IRB entity has required modifications to the protocol or consent documents as a result of the event

Yes →

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

No → No need to report as a UP.

Yes →

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 →

UPs should be submitted within 7 days of becoming known. For Internal UPs, use the Report Form in eIRB, for External UPs, the Amendment Form. If a paper protocol, use the Change in Protocol (CIP) form. UPs that are also SAEs (See SAE Decision Tree) should be submitted on the SAE Form according to SAE timelines.

Any changes to the protocol/materials in response to the event should be done promptly via an Amendment (CIP for paper protocols). Notify the IRB (irb@slu.edu) immediately if implementing modifications for subject safety prior to IRB review and approval and also report the Protocol Deviation.

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