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

Is the event related or possibly related to participation in the research?  
- No → Event is not reportable to SLU IRB.
- Yes → Did the event occur at SLU or a SLU affiliated site?
  - No → Event is not reportable to SLU as an SAE, but may still be an Unanticipated Problem (UP). Please see UP Decision Tree.
  - Yes → Is the event life threatening or did it result in death?
    - 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 3 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 → 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.

SAEs are to be reported on the SAE Form in eIRB.
Studies not in eIRB can use the paper SAE Form.

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