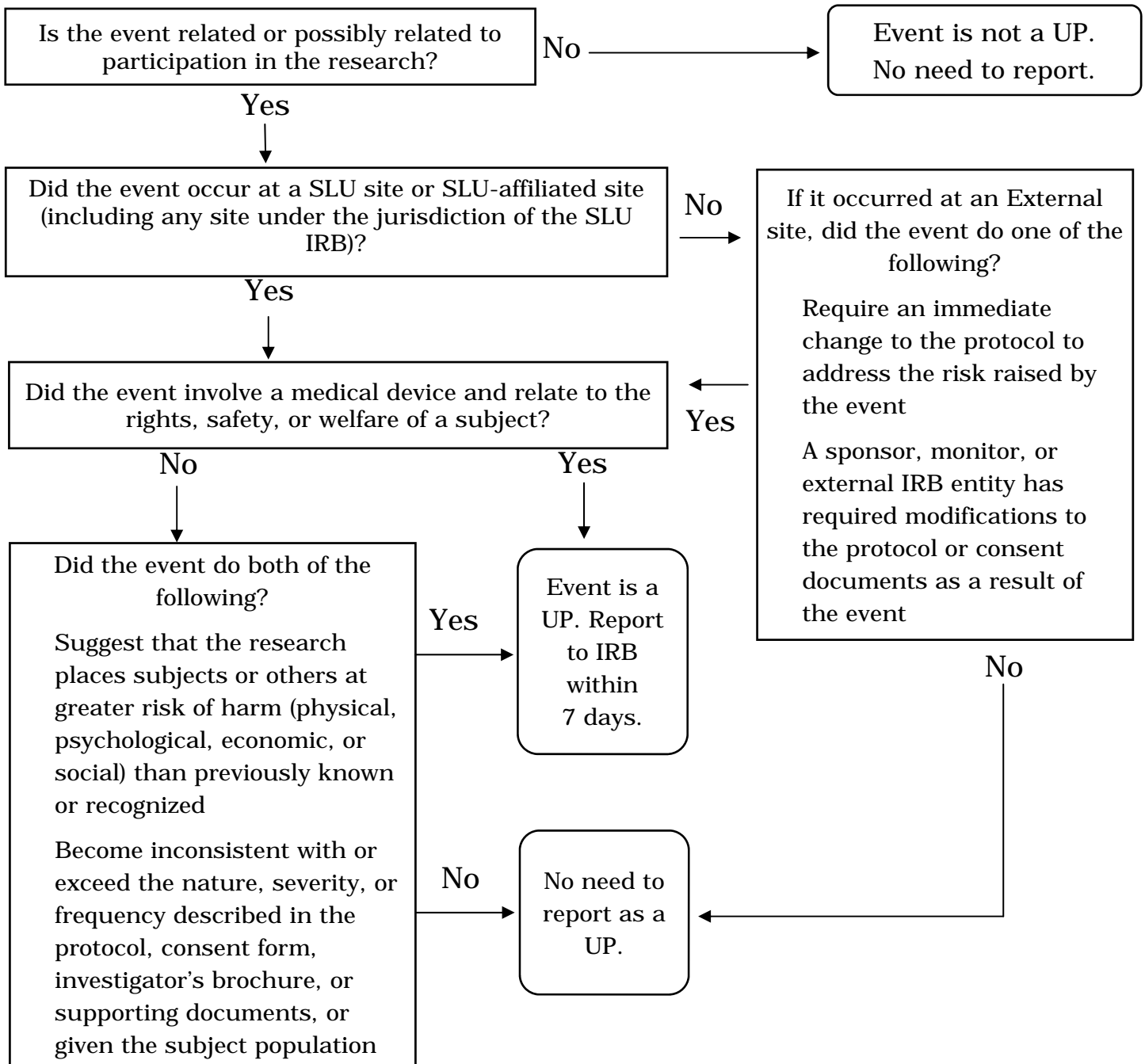


Saint Louis University Institutional Review Board

Unanticipated Problem (UP) Decision Tree



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.