

Memo

To: Saint Louis University (SLU) Research Community
From: Melissa Fink, MA, CIP, SLU IRB Director
Date: January 12, 2015
Re: Submission of Serious Adverse Events (SAE)

As a reminder, the SLU IRB does not require submission of SAEs that occur at external sites that are not under the jurisdiction of the SLU PI and SLU IRB. For example, in a multi-site clinical trial, if a SAE occurs at a non-SLU site that is under the direction of a non-SLU site PI, submission of that SAE does not need to occur at SLU. If the SAE occurs at a non-SLU site that is under the direction of a SLU PI (such as a nursing home in which the SLU PI is conducting the research), this is considered an internal, reportable SAE.

In addition, SLU IRB does not require submission of SAEs that are deemed unrelated to the research by the SLU PI with concurrence by the study sponsor, if applicable. So, despite the event meeting the criteria of an SAE (e.g., death or hospitalization), if the event has been deemed unrelated to the research, this event does not need to be reported to the SLU IRB. Instead, note this determination in the research record with justification and if necessary, file a copy of this policy memo and/or provide to sponsors who are requesting documentation that the local IRB has reviewed.

The SLU IRB will begin to return (not review) submissions of external and/or unrelated SAEs as neither the federal regulations nor SLU policies require local IRB review of them. These requirements are also detailed in the SLU IRB Requirements for Reporting Events Relating to Subjects/Subject Safety which can be found on the SLU IRB website at https://www.slu.edu/research/faculty-resources/research-integrity-safety/institutional-review-board-irb/irb_assets/guidelines_reportable_events.doc.

Questions or concerns can be directed to irb@slu.edu or 314-977-7744.

Thank you for your cooperation.