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Protocol Violation Report Form

Institutional Review Board
Assurance No. FWA00005304

Instructions:

This form should be used to report protocol violations (PVs), defined here as any variation from the approved research protocol (whether intentional or unintentional) that occurred without prior IRB approval/notification during the conduct of research at SLU or an affiliated site. PVs may occur due to researcher error, or they may occur without control of the research team (i.e., participant non-compliance). Consent violations that are more than minor should also be reported here (see guidelines). Please refer to the Protocol Violation Decision Tree for additional guidance.

An unintentional PV that was previously identified by the research team does not need to be reported here if the existing study record documents a qualified determination that the incident did not place the participant(s) or others at a greater risk of harm

Study teams are responsible for maintaining this form (as well as the IRB's acknowledgment) within the overall regulatory binder.

- Please do not include previously IRB-reviewed violations.
- Please upload any related documents (e.g., PI concurrence letters with signature, sponsor notification, sponsor report form, monitoring letters, etc.).

Date:	IRB #:
Principal Investigator:	Phone/Pager:
Department:	Email:
Contact Person:	Phone/Pager:
	E-mail:
Study Title:	

Date of event/incident:			
Date event/incident identified:			
Is this study receiving external funding?		☐ Yes ☐ No	
If externally funded, was the sponsor notified of the event/incident?		☐ Yes ☐ No	☐ N/A
Date of sponsor notification:			☐ N/A
If SLU is relying on another IRB for oversight, was the event/incident reported to the Reviewing IRB?		☐ Yes ☐ No	☐ N/A

Provide a full description of the protocol violation, including why the event/incident occurred:	
Disclose whether the event/incident had an effect on the subject's rights, safety or welfare, and/or on the integrity of the data: If so, what was done to rectify the safety/welfare/integrity issue? If not, please describe why. This should be confirmed by PI (or other qualified study personnel. For medical studies, this should be confirmed by a qualified medical study personnel [e.g., MD, DO, RN]).	
What will be done in the future to prevent recurrence of the violation (i.e., research personnel re-education; quality assurance monitoring)? If this was a consent/HIPAA documentation error, describe the plans for re-obtaining consent/HIPAA Authorization or provide justification if no such plans exist.	
Will this result in a change to the protocol? If not, please justify.	