Reporting Timeframes

Type of Event	Reporting Timeframe*
ADVERSE EVENTS	
On-site adverse event that the PI determines to be a UPR (definitely, probably or possibly related to the research and serious or unexpected) or expected and related to the research that indicates a higher frequency of occurrence or higher level of severity than previously known	**Within 10 working days of awareness**
Off-site adverse event that the PI determines changes the study risks or benefits or requires modification to currently approved study documents including Research Plan and/or consent/assent documents	
On-site death that the PI determines to be unexpected and related or possibly related to the research	**Within 24-hours of awareness**
On-site adverse event that the PI determines does not meet criteria for a UPR	**At the time of Continuing Review**
Off-site adverse events that do not meet the criteria for 10-working-day reporting (see above)	
PROTOCOL DEVIATIONS, VIOLATIONS AND INCIDENTS	
Major deviation/violation (for example: instances that impact participant safety, substantially alter risks to participants, are non-compliant with applicable UCSD HRPP, federal, state and institutional policies and regulations)	**Within 10 working days of awareness**
Any deviation from the protocol taken without prior IRB review to eliminate apparent immediate hazard to a research subject	
An event or incident that meets the criteria for an unanticipated problem involving risk to participants or others	
Minor deviation/violation (for example: failure to perform a required lab test or perform a study visit/study labs during the required time frame, that, in the opinion of the PI, does not affect subject safety or data integrity)	**At the time of Continuing Review**
OTHER TYPES OF EVENTS OR UPDATED STUDY INFORMATION	
Audit or Monitoring report with significant findings and/or that addresses risks or benefits of the research	**Within 10 working days of awareness**
DSMB/DSM report that addresses risk(s) or benefit(s) of the research	
Hold, suspension, termination of study activities	
Updated Protocol, Investigator Brochure, or Device Brochure that addresses risk(s) or benefit(s) of the research	
Other updated study information that addresses risk(s) or benefit(s) of the research	
Audit or Monitoring report without significant findings and/or that addresses risk(s) or benefit(s) of the research	**Within 30 working days of awareness**
DSMB/DSM report that does not address risk(s) or benefit(s) of the research	
Updated Protocol, Investigator Brochure, or Device Brochure that does not address risk(s) or benefit(s) of the research	
Other updated study information that does not address risk(s)or benefit(s) of the research	

*The VA may have a different timeframe for reporting these events. For more information, please see the SOPP, section 3.13, Reporting Adverse Events and Unanticipated Problems, page 4, and/or contact the VASDHS IRB at (858) 552-8585 x 2891.