Document 24

United States Air Force Academy (USAFA)

Human Research Protection Program (HRPP)

Deviations, Problems and Adverse Events Reporting Guideline

The USAFA HRPP requires Principal Investigators (PI) to promptly report the following events using the USAFA HRPP Deviations, Problems, and Safety Reporting Form.

EVENT	TIMELINE
• ***An Unanticipated problem involving risks to subjects or others (UPIRSO)-*** includes any incident, experience, or outcome that meets **all** of the following criteria: 1. ***Unexpected*** (in terms of nature, severity, or frequency) given the procedures as described in the protocol documents (e.g., the IRB-approved research protocol and informed consent document) and the characteristics of the subject population being studied; 2. ***Related or possibly related*** to participation in the research (possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by procedures involved in the research); and 3. ***Suggests that the research places subjects or others at a greater risk of harm*** (including physical, psychological, economic, or social harm) than was previously known or recognized, even if no harm has actually occurred. An adverse event (AE) could be considered "unanticipated problem involving risks to subjects or others	If the event is life-threatening report within **1 calendar day** of receipt of the information**.** All other events/problems must be reported within **7 calendar days** of the investigator's receipt of the information.
• ***All Research-Related Deaths*** (whether anticipated or unanticipated)	Immediately upon receipt of the information
• ***Other events (anticipated or unanticipated) that in the PI's judgment, warrants reporting or is in the best interest of the subject(s)*** (e.g., because it may affect the safety and/or welfare of subjects; it changes the risk level of the study; or the frequency of the same event significantly increases)	If life-threatening, report within 1 calendar day of receipt of the information. All other events/problems must be reported within 7 calendar days of the investigator's receipt of the information.
• ***Other unanticipated problems that impact the conduct or integrity of the study*** (e.g. FDA Clinical hold or recall, Published literature or data and safety monitoring board report impacting risk-benefit ratio, FDA Form 483 or warning letter, investigator medical license restriction or suspension, participant is incarcerated)	If life-threatening, report within 1 calendar day of receipt of the information. All other events/problems must be reported within 7 calendar days of the investigator's receipt of the information.
• ***Any exception or deviation that is not approved by the IRB prior to its initiation or implementation*** *(whether it does or doesn't affect risk).*	Exceptions or deviations that are designed to mitigate newly discovered risks to subjects may be implemented without prior IRB approval, but must be reported to the IRB within 7 days. All other deviations or exceptions may not be implemented without prior IRB approval.