UCSF Office of Ethics and Compliance
Human Research Protection Program

Post-Approval Reporting Requirements Summary Sheet

Federal regulations and the UCSF IRB/HRPP require investigator reporting of any post-approval research-related event or information that may meet the HRPP's institutional definitions of "*unanticipated problem involving risk to participants or others*" or "*serious or continuing noncompliance*." The IRB determines whether these definitions apply when evaluating investigator event reports. The following table summarizes which types of events or information should be reported to the IRB/HRPP, the reporting window and appropriate reporting form to use.

See the Adverse Event and/or Protocol Violation or Incident sections of the UCSF HRPP website for definitions and details. Questions? Contact the IRB at 415-476-1814 or IRB@ucsf.edu and ask to speak with the QIU (Quality Improvement Unit) Analyst of the day.

What, When, and How to Report to the HRPP

Type of Event	When to Report*	Reporting Form
* The SFVAMC has a shorter timeline and different definitions than UCSF for reporting certain categories of post- approval events. (The website pages noted above include links to the relevant SFVAMC information.)		
ADVERSE EVENTS		
Internal (on-site) adverse event that PI determines to be 1. Definitely, probably or possibly related *AND* 2. Serious or unexpected	Within **5 working days** of UCSF PI awareness **Internal, related deaths and life-threatening events:** Report **immediately**	iRIS Adverse Event Reporting Form
External (off-site) adverse even that UCSF PI determines • changes the study risks or benefits, *OR* • necessitates modification to the IRB-approved consent document(s), and/or the IRB-approved application/protocol	Within **10 working days** of UCSF PI awareness	iRIS Adverse Event Reporting Form
OTHER TYPES of EVENTS or SAFETY INFORMATION		
Audit or Monitoring Report with significant findings	Within **10 working days** of awareness	iRIS Reporting Form
DSMB/DMC Report		
Hold on Study Activities due to unexpected risk or required by any oversight entity e.g. UCSF, FDA, OHRP		
Updated Investigator Brochure		
Other Safety Information or Publication	**Change** to risk language: Within **10 working days** of awareness **No change** to risk language: **Reporting not required**	iRIS Reporting Form
Pharmacy Packet Inserts		
PROTOCOL VIOLATIONS and RESEARCH-RELATED INCIDENTS		
Major Violation including, but not limited to incorrect intervention given, enrollment of ineligible participant, key safety procedure/lab not done or done outside window.	Within **10 working days** of awareness	iRIS Protocol Violation/Incident Report Form
Immediate Protocol Change to Protect Participant Safety	Within **10 working days** of occurrence	
Major Incident including, but not limited to problem with consent or recruitment process, significant complaint or concern, lapse in study approval, loss of adequate resources, potential breach of confidentiality or privacy.	**Potential breaches of privacy or confidentiality:** Within **48 hours** of awareness **Other Major Incidents:** Within **10 working days** of awareness	