

## 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 QIU by one of the following: submit an [Ask Andy Form](#), email: [ucsfQIU@ucsf.edu](mailto:ucsfQIU@ucsf.edu) or [IRB@ucsf.edu](mailto:IRB@ucsf.edu) or call: 415-476-1814, 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.)		
<b>ADVERSE EVENTS</b>		
<b>Internal (UCSF is IRB of record) adverse event</b> that PI determines to be 1. Definitely, probably or possibly related <i>AND</i> 2. Serious or unexpected	Within <b>5 working days</b> of UCSF PI awareness  <b>Internal, related deaths and life-threatening events: Report immediately</b>	iRIS Adverse Event Reporting Form
<b>OTHER TYPES of EVENTS or SAFETY INFORMATION</b>		
<b>Audit or Monitoring Report</b> with significant findings	Within <b>10 working days</b> of awareness	iRIS Reporting Form
<b>DSMB/DMC Report</b>		
<b>Hold on Study Activities</b> due to unexpected risk or required by any oversight entity e.g. UCSF, FDA, OHRP		
<b>Other Safety Information or Publication</b>	<b>Change</b> to risk language: Within <b>10 working days</b> of awareness	iRIS Reporting Form
<b>Pharmacy Packet Inserts</b>	<b>No change</b> to risk language: <b>Reporting not required</b>	
<b>Investigational Brochures</b>		
<b>PROTOCOL VIOLATIONS and RESEARCH-RELATED INCIDENTS</b>		
<b>Major Violation</b> including, but not limited to incorrect intervention given, enrollment of ineligible participant, key safety procedure/lab not done or done outside window.	Within <b>10 working days</b> of awareness	iRIS Protocol Violation/Incident Report Form
<b>Immediate Protocol Change to Protect Participant Safety</b>	Within <b>10 working days</b> of occurrence	
<b>Major Incident</b> 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.	<b>Potential breaches of privacy or confidentiality: Within 48 hours of awareness</b>  <b>Other Major Incidents: Within 10 working days</b> of awareness	