UCSF Human Research Protection Program (HRPP)
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.

- Privacy Related Incidents must also be reported directly to the applicable Privacy Office as well as the IRB of Record. Learn more here.
- All reporting guidelines apply to research conducted internationally.
- UCSF reporting requirements apply to all sites relying on the UCSF IRB.
- Studies relying on an external IRB are required to report to the external IRB only.

Questions: Contact the QIU by one of the following: submit an Ask Andy Form, email ucsfQIU@ucsf.edu or irb@ucsf.edu, or call 415-476-1814 to speak with the QIU (Quality Improvement Unit) Analyst of the day.	Resources: See the Adverse Event and/or Protocol Violation or Incident sections of the UCSF HRPP website for definitions and details.

What, When, and How to Report to the HRPP

Type of Event	When to Report*		Reporting Form
ADVERSE EVENTS			
Internal (UCSF is IRB of record) 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 (occurs at a site where UCSF is *not* the IRB of record) adverse event that sponsor 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 awareness		iRIS Adverse Event Reporting Form
OTHER TYPES of EVENTS or SAFETY INFORMATION			
• Audit or Monitoring Report with significant findings • DSMB/DMC Report • Hold on Study Activities due to unexpected risk or required by any oversight entity e.g. UCSF, FDA, OHRP	Within *10 working days* of awareness		iRIS Reporting Form
• Investigator's Brochure	IB updates important to subject safety = prioritize the submission. Otherwise, submit in a timely manner.		iRIS Reporting or Modification Form
• Medwatch Reports • External Safety Reports • Other Safety Information or Publication • Pharmacy Packet Inserts	Change to risk language: Within *10 working days* of awareness	No change to risk language: Reporting not required	iRIS Reporting Form

<table>
<tr><th colspan="4">PROTOCOL VIOLATIONS and RESEARCH-RELATED INCIDENTS</th></tr>
<tr><td>Major Violation including, but not limited to incorrect intervention given, enrollment of ineligible participant, key safety procedure/lab not done or done outside window.</td><td colspan="2">Within 10 working days of awareness</td><td rowspan="3">iRIS Protocol Violation/Incident Reporting Form</td></tr>
<tr><td>Immediate Protocol Change to Protect Participant Safety</td><td colspan="2">Within 10 working days of occurrence</td></tr>
<tr><td>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.</td><td>Potential breaches of privacy or confidentiality:
Within 48 hours of awareness</td><td>Other Major Incidents: Within 10 working days of awareness</td></tr>
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* The SFVAMC has a shorter timeline and different definitions than UCSF for reporting certain categories of post-approval events.

Last Updated October 2023