

UCSF Human Research Protection Program HRPP Post-Approval Reporting Requirements Summary Sheet for Principal Investigators

Federal regulations and the UCSF CHR/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 continuous noncompliance](#). The CHR 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 CHR/HRPP, and indicates the reporting window and appropriate reporting form to use.

Post-Approval Reporting Requirements: What, When & How to Report to the HRPP

Type of Event	When to Report	Reporting Form
<u>ADVERSE EVENTS</u>		
<u>Internal (on-site) adverse event</u> that PI determines to be: <ul style="list-style-type: none"> • Definitely, Probably or Possibly related AND • Serious or Unexpected 	Report within 10-working-days of UCSF PI awareness.	10-Working-Day Internal [On-Site] Reporting Form
<u>External (on-site) adverse event</u> that UCSF PI determines: <ul style="list-style-type: none"> • changes the study risks or benefits, OR • necessitates modification to the CHR-approved consent document(s), and/or the CHR-approved application/protocol 	Report within 10-working-days of UCSF PI awareness.	10-Working-Day External [Off-Site] Reporting Form
Internal [on-site] death unrelated to research, as determined by the UCSF PI	Reporting required for interventional studies only. Report at time of renewal or major modification.	AE Summary Log
External (off-site) adverse event that does not meet the CHR 10-working-day reporting criteria, as determined by the UCSF PI	<u>Reporting not required.</u> However, may be reported at sponsor request at renewal, major modification or study closure.	
<u>OTHER TYPES of EVENTS or SAFETY INFORMATION</u>		
Audit or Monitoring Report with significant findings	Within 10-working-days of awareness	Reporting Form for Investigator Brochure, DSMB Report, Safety Information, Audit, and Hold on Study Activity
DSMB/DMC Report		
Other Safety Information or Publication that suggests a change to the risk or benefit of the research		
Hold on Study Activities due to unexpected risk		
Updated Investigator Brochure		
<u>PROTOCOL VIOLATIONS and RESEARCH-RELATED INCIDENTS</u>		
<u>Major Violation</u> 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	Violation/Incident Reporting Form
Immediate Protocol Change to Protect Participant Safety	Within 5-working-days of occurrence	
<u>Major Incident</u> Including, but not limited to: problem with consent or recruitment process, significant complaint or concern, lapse in study approval, loss of adequate resources, breach of confidentiality.	Within 10-working-days of awareness	