

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. The Privacy Office should be notified if the incident is Privacy related.

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 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<br>1. Definitely, probably or possibly related AND<br>2. Is EITHER:<br>Serious and unexpected<br>OR<br>Serious and more frequent or severe than expected   | Within 5 <i>working days</i> of UCSF PI awareness  | Internal, related deaths and life-threatening events:<br>Report immediately | iRIS Adverse Event Reporting Form |
| <u>External</u> (occurs at a site where UCSF is <i>not</i> the IRB of record) <u>adverse event</u> that sponsor determines<br>• changes the study risks or benefits, OR<br>• necessitates modification to the IRB-approved consent document(s), and/or the IRB-approved application/protocol | Within 10 <i>working days</i> of awareness   |   | iRIS Adverse Event Reporting Form |
| OTHER TYPES of EVENTS or SAFETY INFORMATION  |  |   |                                   |
| • Audit or Monitoring Report with significant findings<br>• DSMB/DMC Report<br>• Hold on Study Activities due to unexpected risk or required by any oversight entity e.g. UCSF, FDA, OHRP  | Within 10 <i>working days</i> of awareness   |   | iRIS Reporting Form               |
| • Investigator’s Brochure<br>• Pharmacy Packet Inserts   | IB updates important to subject safety = prioritize the submission.<br><br>Otherwise, submit in a timely manner. |   | iRIS Modification Form            |

|  |  |  |                     |
|--|--|--|---------------------|
| <ul style="list-style-type: none"> <li>Medwatch Reports</li> <li>External Safety Reports</li> <li>Other Safety Information or Publication</li> </ul> | Change to risk language:<br>Within <i>10 working days</i> of awareness | No change to risk language:<br>Reporting not required unless required by sponsor or funding agency | iRIS Reporting Form |
|--|--|--|---------------------|

| 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. <b>Any event that the IRB has determined requires reporting.</b>  | Within <i>10 working days</i> of awareness   |   | iRIS Protocol Violation/Incident Reporting Form |
| Immediate Protocol Change to Protect Participant Safety   | Within <i>10 working days</i> 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. <b>Any event that the IRB has determined requires reporting.</b> | Potential breaches of privacy or confidentiality:<br><i>Within 48 hours of awareness</i> | Other Major Incidents: Within <i>10 working days</i> of awareness |   |

\* The [SFVAMC](#) has a shorter timeline and different definitions than UCSF for reporting certain [categories of post-approval events](#).

*Last Updated March 2024*