



University of California  
San Francisco

Published on *UCSF Institutional Review Board* (<http://irb.ucsf.edu>)

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## **Responding to and Reporting Research-Related Concerns and Complaints**

### **Responding to Participant Concerns or Complaints**

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**If you are a study participant or other individual who wishes to report a concern or complaint, please visit [this page](#)<sup>[1]</sup>.**

### **Responding to Participant Concerns or Complaints**

We are concerned about the safety, rights and welfare of all individuals participating in research projects at UCSF and its affiliated sites. We take all research concerns or complaints that are reported to us very seriously.

As a study investigator, you and/or your staff are obligated to make a good faith effort to promptly respond to ? and to try to resolve ? any study-related concern or complaint you receive or of which you are aware.

#### **Reporting a Significant Participant Concern or Complaint to the IRB**

You must report any significant complaint or concern to the IRB as a study-related incident <sup>[2]</sup>. A complaint/concern is significant if it may adversely impact a participant?s or a potential participant?s safety, rights or welfare. Additionally, any complaint/concern that requires a

change to the study protocol or consent form is considered significant.

Please note that most reported concerns and complaints are minor and routine, e.g., a subject complaint about late study payment. **You do not need to report minor or routine concerns that can be resolved quickly to the IRB.**

## **When the HRPP Receives Concerns or Complaints Directly**

We are obligated to receive and respond to concerns and complaints reported to us directly <sup>[1]</sup>. Complaints are submitted in a variety of ways and from a number of different sources, including research participants, the public, faculty, staff and government agencies.

When this occurs, we will attempt to resolve minor concerns or complaints with the complainant informally, often referring the participant back to the study team. If we judge the concern or complaint to be significant, it must be investigated in a more formal manner.

### **Page last updated:**

Jan 25, 2016

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**Source URL:** <http://irb.ucsf.edu/responding-and-reporting-research-related-concerns-and-complaints>

### **Links**

[1] <http://irb.ucsf.edu/reporting-research-concerns-and-complaints>

[2] <http://irb.ucsf.edu/protocol-violation-or-incident>