



**UCSF**

University of California  
San Francisco

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# Human Research Protection Program Training

## *UCSF's Subject Injury Program*

*~ Overview ~*

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# Outline

- **Common elements of an injury claim**
- **What is a subject injury**
- **Who identifies an injury event**
- **How to report an injury event**
- **How UCSF's Subject Injury Program works**
- **How the UCSF SI Program can help you with an SI claim**
- **Questions and Discussion**

# Research Risk Management

**476-4171**

or

**514-2869**

**Human  
Research  
Protection  
Program**

# Common elements of an injury claim

- **Urgent**
- **Stressful and labor-intensive**
- **Disruptive to routine research operations**
- **Potentially *very* costly**
- **Complex: Involve a number of campus departments and stakeholders**
  - Legal; Financial Services; Industry Contracts

## What is a Subject Injury?

An “injury” is an:

- **Illness or harmful event**
- **Directly related (definitely, probably or possibly) to a research study intervention, procedure or test**
- **Generates medical treatment costs**

And is *not* a:

- **Natural progression of pre-existing condition(s)**
- **Complication of conventional care**

## Who identifies that an event is a possible subject injury (i.e., a claim)?

- **Study participant**
- **Study Principal Investigator**
  - And/or the Study Coordinator or other staff or co-PI with the Study PI's concurrence
- **Other:**
  - CHR Committee
  - Subject's relative or advocate

# How do you report a possible subject injury claim?

- **Call Research Risk Management *Immediately***
  - If you know or suspect that a research injury has occurred
- **CHR/HRPP Post-Approval Reporting Forms**
  - Adverse Event
  - Violation/Incident Form

## How does UCSF's Subject Injury Program work?

- **All subject injury claims go to a the UCSF Subject Injury Program**
  - Operates under campus Risk Management
- **Claims are initially vetted and managed by a campuswide committee called the *Subject Injury Group (SIG)***



## How does UCSF's Subject Injury Program work?

- **The SIG (for UCSF) makes recommendations about payment of claims to the systemwide Subject Injury Program at UC's Office of the President (UCOP)**
- **UCOP SI Program makes final determinations about claims coverage and payment**

## How can the UCSF Subject Injury Program help you with a claim?

- **Investigate validity of claims**
  - Work with the UCOP SI Program's third party administrator to collect and evaluate research and other medical records
- **Communicate directly with study participants for questions or concerns about:**
  - The local or systemwide SI Programs
  - The status of their claim

## How can the UCSF Subject Injury Program help you with a claim?

- **Help arrange and coordinate followup treatment**
  - Preference is to keep the subject's medical care at UCSF (or another UC campus)
- **Manage the research and health insurance billing processes**
  - Including health coverage and billing "holds"
- **Coordinate with Office of Sponsored Research (for industry-sponsored studies)**
  - Review of indemnification sections of CTAs

# Resource Information

**Please contract us for more information about the Subject Injury Programs at UCSF and UCOP, or for in-person trainings for you or you staff on this or any other aspects of *Clinical Research Risk Management!***

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