



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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