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Human Research Protection Program Training

UCSF's Subject Injury Program

Wednesday, April 11, 2012

11:30 am to 12:00 pm

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Outline for Today

- **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 an injury claim is pending
 - If the study PI or other personnel receive a legal notice
- **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 *Subject Injury Group (SIG)* that includes:**
 - HRPP/CHR; campus Risk Management; Medical RM/Professional Liability; Industry Contracts Division; plus Campus Legal Counsel for Health Affairs and the AVC Ethics and Compliance

How does UCSF's Subject Injury Program work?

- The SIG makes *recommendations* about payment of claims to the UCOP Subject Injury Program
- 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 participant 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 billing process through Patient Financial Services**
 - Including billing “holds”
- **Coordinate with Office of Sponsored Research (for industry-sponsored studies)**
 - Review of indemnification sections of CTAs

Question #1

- **For most eligible injury claims, is the subject's insurance or health plan billed?**

Question #2

- About how long does it take to determine that a claim is eligible for coverage and to settle the case?

Resource Information

Research Risk Management:

- 476-4171
- **Carroll.Child@UCSF.edu**
- Carroll Child, RN, MSc, CCRP (Clinical Research Risk Manager)
- RM website:
- <https://www.rmis.ucsf.edu/Default.aspx>
- Treatment and Compensation section of HRPP Website:
- http://www.research.ucsf.edu/chr/guide/chrH_Injury.asp

Questions?

