Human Research Protection Program Training

UCSF’s Subject Injury Program

Wednesday, April 11, 2012
11:30 am to 12:00 pm
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
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?