

# Cost Benefits of an Institutionally-Based Subject Injury Treatment and Management Program

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## Problem/Issue:

Despite a 2002 Institute of Medicine report calling for research organizations to provide compensation to research participants directly injured in research and in the absence of federal or other national regulatory or accreditation requirements mandating the provision of compensation to injured subjects, work by Steinbrook (*NEJM*, 2006) found that only a small minority (16%) of the 102 academic medical centers surveyed had policies for the provision of free care or treatment for study-related injury. At the same time, there is a paucity of information about the number of such injury cases occurring in academic research enterprises and the actual cost of responding to such cases through an institutionally-based subject injury treatment and management program.

## Objectives:

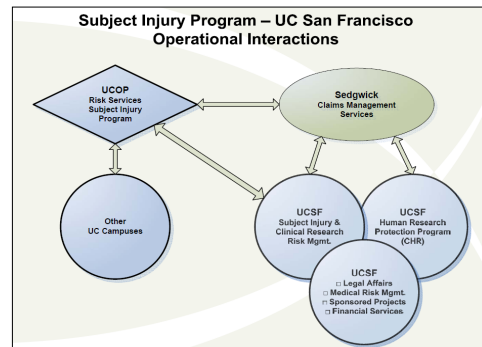
To evaluate the incidence and treatment costs of subject injury events within the Subject Injury (SI) Program at UCSF and the cost differences between research injury claims that were litigated versus those managed through the campus SI Program.



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## Background:

In 2005 the University of California, San Francisco (UCSF) established a campus-based Subject Injury (SI) Program to operationalize the existing University of California systemwide Subject Injury Policy. Working in partnership with key campus entities (the Human Research Protection Program, Office of Legal Affairs, Sponsored Projects and Risk Management) and the University of California Office of the President, UCSF's campus-level SI program initially assesses and manages all subject injury claims arising from UCSF-affiliated clinical research.



## Methods:

During the first quarter of 2010, the UCSF Subject Injury program conducted a retrospective review and analysis of all SI claims/cases filed with the program between January 2006 and December 2009. A Total of twelve (14) claims/cases were analyzed.

## Specific Goals/Aims of Analysis

### To measure the:

- 1) Total number of subject injury cases potentially incurring payment costs
- 2) Total number of subject injury cases actually incurring payment costs
- 3) Cost differences between SI cases that were litigated versus those that were managed within the University SI Program (i.e., did not result in litigation).

## Results:

**Subject Injury Program**  
 University of California, SF  
 Cost of All SI Claims (n=14): Litigated versus Not  
 (January 2006 through December 2009)

	Total Claims	Total Cost	Average Cost/Claim
Claims Litigated or in Litigation	3	\$362,368*	\$120,789
Claims Not Litigated	3	\$73,017**	\$24,339
Additional claims***	8	0	0

\*Professional liability claim reserves on three SI claims in litigation  
 \*\*Total liabilities against UCOP Subject Injury fund for claims managed by CHRM  
 \*\*\*Includes claims denied because they did not meet SI Program criteria

**Table 1. Actual Cost of Litigation vs. Non-litigated Subject Injury Claims:** Of all claims/cases filed (14), half incurred costs. Of the cases incurring costs (6), half (3) were litigated outside of the SI program and the remaining half (3) were managed and settled within the SI program. The remaining eight cases did not meet the SI Program's cost coverage requirements.

## Outcomes of Subject Injury Cases (2006 thru 2009)

### Overall

- ◆ Total of fourteen (14) claims analyzed
- ◆ Of all claims (6) incurred costs for UC
- ◆ Three claims that incurred costs went to litigation (~20% of all claims)

### Litigated claims were:

- ◆ Nearly 5 times greater in total and average cost per claim

### Remaining eight claims findings:

- ◆ No significant/residual injury requiring treatment, or
- ◆ Injuries were unrelated to research, or
- ◆ Costs were covered by alternate payer (private insurance, Medicare, industry sponsor)

**Table 2. Case Outcomes:** Payment costs for the litigated claims (indemnity and attorney fees) were, on average five-times greater than those for non-litigated claims. All other claims (8) were found to have either no injury requiring treatment; were determined to be unrelated to research; or the injuries found to be appropriately charged to an alternate payer (insurance, industry sponsor) resulting in additional cost savings to the UC/UCSF Subject Injury Programs.

## Conclusions:

While further inter-institutional comparative analysis is needed to better characterize the practical value programs designed to compensate participants for treatment costs related to research injury, our review suggests that significant cost benefits may result when injury claims/cases are managed within an institutionally-based SI treatment compensation program. Cost savings may be due to a number of factors that include: 1) a relatively low frequency of claims litigated, 2) comparatively low cost of non-litigated settlements and/or 3) a high percentage of claims settled or closed without incurring direct costs to the compensation program.

## References

- (1) Steinbrook, R. 2006. Compensation for research subjects. *New England Journal of Medicine* 354:1871-1973
- (2) Institute of Medicine. Responsible research: a systems approach to protecting research participants. Washington, DC: National Academy Press, 2003

## For further information

Please contact:  
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 More information on this poster and related clinical research risk management programs can be found at: <https://www.rm.is.ucsf.edu>

