

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

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Problem/Issue:

In the absence of federal or other national regulatory requirements mandating the provision of compensation to subjects injured during their participation in research, work by Steinbrook ⁽¹⁾ in 2006 found that only a small minority (16%) of the 102 academic medical centers surveyed had policies for the provision of care or treatment for study-related injury. At the same time, there is little information about the cost effectiveness of responding to subject injury (SI) cases and claims through an established, institutionally-based SI treatment compensation program. ⁽²⁾

Objectives:

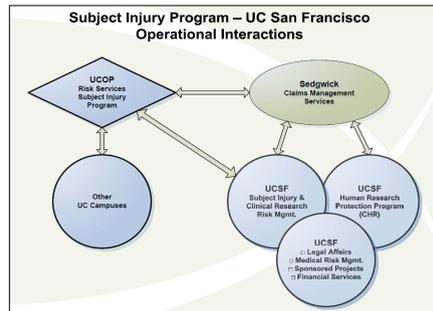
To determine the cost differences between litigated subject injury claims and cases managed within a collaborative subject injury program administered by the University of California Office of the President (UCOP) in partnership with a campus-level Subject Injury Program at the University of California, San Francisco (UCSF).



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Background:

In 2005 the University of California, San Francisco (UCSF) established a campus-based Subject Injury (SI) Program to more fully 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 2009, 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 2008. A Total of twelve (12) 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.

Results:

Subject Injury Program University of California, SF Cost of All SI Claims (n=12): Litigated versus Not (January 2006 through December 2008)			
	Claims Incurring Cost	Total Cost	Average Cost/Claim
Claims Litigated or In Litigation	3	\$362,368*	\$120,789
Claims Not Litigated	3	\$18,020**	\$6,006
Additional claims***	6	0	0

* Professional liability claim reserves on three SI claims in litigation
 ** Total paid by UCOP Subject Injury Fund for claims managed by CRRM
 *** 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 (12), 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 six cases did not meet the SI Program's cost coverage requirements.

Outcomes of Subject Injury Cases (2006 thru 2008)

Overall

- ◆ Total of twelve (12) claims analyzed
- ◆ Half the claims (6) incurred costs for UC
- ◆ Three claims that incurred costs went to litigation (25% of all claims)

Litigated claims were:

- ◆ 2.5 times greater in total cost
- ◆ Over 20 times greater in average cost per claim

Remaining six 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: Payments for litigated claims (indemnity and attorney fees) were, on average, twenty-times greater than those for non-litigated claims. Costs for non-litigated cases represent both actual payments and settlement offers made by the UC SI Program. The remaining six claims incurred no direct costs to settle, resulting in additional savings to the UC Subject Injury Program.

Conclusions:

Review and analysis of subject injury claims and cases arising at a large academic medical center across a two year period suggest that significant cost benefits may result when subject injury cases/claims are managed and settled within an institutionally-based SI treatment compensation program as opposed to litigation and that a significant number of SI claims (50%) can be resolved without sustaining any direct payment costs to the 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

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For further information

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https://www.rmis.ucsf.edu

