**Objectives:**
To determine the cost differences between litigated subject injury claims and cases managed within a collaborative, institutionally-based Subject Injury Treatment and Management Program (SI Program) at the University of California, San Francisco (UCSF).

**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 (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.

**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.

**Results:**
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.

<table>
<thead>
<tr>
<th>Claims</th>
<th>Litigation Cost</th>
<th>Non-litigation Cost</th>
<th>Total Cost</th>
<th>Average Cost/Claim</th>
</tr>
</thead>
<tbody>
<tr>
<td>Claims incurred for litigation</td>
<td>$300,300</td>
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<td>$120,768</td>
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<tr>
<td>Claims not filed for litigation</td>
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<td></td>
<td>$6,000</td>
<td></td>
</tr>
</tbody>
</table>

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 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:**

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**For further information:**
Please contact: carroll.child@ucsf.edu. More information on this and related programs can be found at: https://www.rmis.ucsf.edu