Beyond Subject Injury: A Comprehensive Clinical Research Risk Management Program

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Objectives

To develop, in partnership with the University of California, San Francisco’s (UCSF) Human Research Protection Program (HRPP), Risk Management, Office of Legal Affairs, Office of Sponsored Research and the major research institutes, schools, and divisions, a broad-based Clinical Research Risk Management program that utilizes risk management trending and root cause analysis methodologies to identify, prevent and reduce a range of research-related risks encompassing but not limited to subject injury, affecting the entire research enterprise at UCSF.

Program Development Phase I: Development of a Subject Injury (SI) Program

Since its initial development in December, 2005, the Clinical Research Risk Management (CRRM) program at UCSF has focused on the clarification and refinement of:

1) Incident-based response processes to ensure timeliness in the reporting, evaluation, and prevention of events for subject injury;
2) Campus-wide procedures and individual roles and responsibilities and implementation of the University of California’s systemswide Subject Injury Policy.

Program Development Phase II: Expansion to a Comprehensive Clinical Research Risk Management (CRRM) Program

Are subject injury cases the only research risks to track and manage – or are they just the tip of the iceberg?

In collaboration with the HRPP, the CRRM will move forward to expand its use of risk management for subject injury to encompass assessment of a broader array of clinical research-related activities, procedures, and structures at UCSF in order to identify those aspects of clinical research that pose potential risk to non-subject participants, and interests of the institution.

As mentioned in Clinical Research and Regulatory Affairs (2), the definitions of a “research participant” can be expanded to include not only the key stakeholders involved in clinical research.

Discussion:

Can an institution’s research enterprise benefit from an analysis-based program that not only assesses and manages subject injury events, but that also tracks and responds to a broader array of clinical research risks by:

- Expanding the scope of risk management assessment to encompass all key individual engaged in the clinical research enterprise (both subject and non-subjects);
- Developing and implementing targeted education/training on risk prevention and mitigation strategies; and
- Constructing a functional evaluation component of the program to facilitate assessment of both the utility and cost effectiveness of the Phase II expansion, and its applicability to other HRPP and research risk management programs?

Table 2. Illustrates that, in addition to the risks of subject injury or harm, investigators, the IRB, study sponsors and the institution engaged in research may also face significant research risks.

In addition to the risks in Table 2, a wide variety of subject injuries may arise from the drugs, devices or biologics being tested; research-related procedures; investigator noncompliance with the approved protocol or failure to perform a study-related procedure correctly.

Diagram 1. The next level of Phase I development will encompass:

1) Analysis of trends and “root causes” of subject injuries and
2) New initiatives to proactively facilitate investigator and key personnel awareness of subject injury safety risks.

Diagram 2. Illustrates numerous areas of risk, in addition to subject injury, that may directly or indirectly impact key personnel involved in the clinical research enterprise at UCSF and to the overall financial, operational, and reputational interests of the institution.