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Development and Implementation of an Evidence-Based, Institution-Wide Clinical Research Risk Management Program

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Topic: Ethics and Risk Assessment

Problem/Issue Statement

Objectives: To develop, in partnership with the UCSF Human Research Protection Program (HRPP), Medical Risk Management, Office of Legal Affairs, Office of Sponsored Research and the major research institutes, schools, and divisions, proactive data-based systems for clinical research oversight to help foster an institutional-wide commitment to preventing or reducing human subject risks at UCSF

Description of Program

Methods: Since its initial development in December, 2005, the Clinical Research Risk Management (CRRM) program has focused on:

- Incident-based response processes to insure maximum timeliness in the reporting, evaluation, and payment of claims for subject injury;
- 2) Clear descriptions of the roles and responsibilities of key individuals across the institution involved in responding subject injury claims; and
- 3) Refinement of the University's Subject Injury Policy related to coverage for claims of injury at UCSF.

From this base, in April, 2008, the CRRM program began its next phase of development with the launching of new campus-wide initiatives to proactively facilitate investigator and key university personnel awareness of research safety risks and requirements for investigators and others involved in the clinical research enterprise at UCSF. Moving forward, the CRRM program is applying risk analysis methodology to:

1) Identify the areas of clinical research that pose potential harm to participants' safety and welfare;
2) Employ incident(case)-based root cause analysis process to direct outreach and safety-related educational and efforts;
3) Conduct focused outreach briefings to share analysis data with key campus stakeholders;
4) With the HRPP, develop and disseminate best research practice training and information; and
5) Provide ad hoc, on-site evaluation and consultation for clinical researchers and their support personnel.

Conclusions: The addition of a comprehensive, risk-based analysis component to the existing post-approval oversight for human research protections facilitates the implementation of a long-standing University-wide subject injury policy and significantly augments efforts to protect the safety and welfare of subjects. By using case and incident-based trending of past subject risk events to guide education and training for investigators and key research personnel, UCSF will be able to learn from its experiences, reduce research risks and lay the ground work for development of benchmark standards to guide research safety efforts campus-wide. In this way, the wide ranging scope and framework of the UCSF Clinical Research Risk Management program may serve as a model for other UC campuses and as well as other large institutionally based clinical research enterprises.