

**Association of Clinical Research Professionals:
Summary of Presentation for March 21, 2005 FDA Hearing
On Reporting of Adverse Events to Institutional Review Boards**

1. Brief description of Association of Clinical Research Professionals (“ACRP”) and purpose for involvement in the hearing.

2. Recognition of the Problem:

ACRP agrees with the observations of the Secretary’s Advisory Committee on Human Research Protections (“SACHRP”) as detailed in its letter to former HHS Secretary Thompson. However, ACRP believes the recommendation offered by SACHRP is only one step, but an essential step, toward beginning to address this issue, and that it does not go far enough.

3. Proposed Solutions:

ACRP believes that there is an immediate need to create and implement a national adverse event reporting system that takes advantage of currently available information technology to address the long-standing and ongoing problems related to reporting adverse events to institutional review boards (“IRBs”).

Such a system can and should serve many specific goals, including: characterizing adverse event profiles for investigational and approved drugs, devices and biologics; protecting human subjects; and as a simple registry of clinical trials serve as a national resource for investigators, IRBs, data and safety monitoring boards, sponsors and regulators charged with responsible conduct of clinical research, and for the public.

Toward this end, a system should fulfill certain design features including:

- Uniformity – There should be a single set of requirements and guidance for adverse event reporting in all clinical trials regardless of the source of funding.
- Simplicity – The system should be readily available to all parties; should utilize a simple, common reporting format that facilitates rather than discourages reporting; and should be independent of a specific technology platform.
- Timeliness and Efficiency – The system should capture information at the point of entry and at the time of entry using technology that eliminates paperwork and redundancy on behalf of either the reporter or the receivers of the reports.

- Accessibility – The system should allow, with appropriate password and tiered firewall protections, access to information in a manner that optimizes the value of and the ability to analyze the information and minimizes the likelihood of harm to research participants and patients. The system should also provide security for truly proprietary, trade secret information, but such proprietary interests should not be allowed to take precedence over the safety and well being of research participants or the public.

Many of these design features can be effectively achieved using web-based, active serve technologies for database entry and mapping in a cost effective manner.

The system should be developed as a shared, critical infrastructure for designing and conducting clinical research and for protecting the safety of research subjects, patients and the public. As such, support for the system should be borne by industrial, governmental and private sponsors of research. A “national trust fund” model analogous to that developed to support the national air transportation safety system may be appropriate.

A prototype system that fulfills most of these criteria has already been developed and implemented by the NIH Office for Biotechnology Affairs and the FDA for high-risk gene-transfer and oncology research. This system has already been demonstrated to the research community and deployed at NIH-supported General Clinical Research Centers, the NIH Clinical Center and at NCI-supported cancer research centers across the country. The system, even though it currently has a limited application, could well serve as the prototype for development of a broad, robust system for adverse event reporting in all disciplines. An investment of federal funds to develop and implement such a system would yield handsome rewards for all parties to the clinical research enterprise and the public.