Trials and Tribulations

by Susan W. Berson, J.D.

As the number of clinical trials increases, so do the opportunities for errors and mistakes. Incomplete oversight of a clinical trial can result in harm to patients, which can create significant civil liabilities for the facility where the trial is conducted. Many people in medicine feel that Institutional Review Boards (IRBs), the bodies charged with approving and overseeing trials at institutions undertaking such trials, are being overloaded and asked to do too much. Uncertainties abound as to whether existing laws can deal with the "new" research coming down the pipeline (i.e., cancer treatments designed to impact individual genetic characteristics).

In the last few years, clinical trials that did not meet IRB criteria have fallen through the cracks simply because the IRBs were overwhelmed with requests for reviews. In some cases, serious patient harm and even death occurred, with the result that government agencies and industry organizations are currently scrutinizing the research programs in this country. Concerns center on inadequate oversight and failure to disclose conflicts of interest, both of which can result in consequences that create significant liability for a cancer center.

The problem is so acute that federal legislation was proposed last year that would have created national standards governing IRBs, and a number of proposals for mandatory or voluntary accreditation standards for IRBs have been developed.

Serious concerns have also arisen over whether compensation or ownership of trials can compromise an investigator's judgment on such issues as when to report an adverse event, whether a participant should be removed from a trial, and even whether a trial should be discontinued entirely. While the Food and Drug Administration regulations and the Common Rule require disclosure of certain financial interests, some people in the industry feel that simple disclosure is not enough to solve potential conflict of interest problems.

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Many in the industry believe that clinical trials will be more heavily regulated at both the federal and state levels; however, the extent of this regulation may depend upon how the industry responds to past errors and voluntarily polices itself in the short term.

The Health Insurance Portability and Accountability Act (HIPAA) has added yet another layer of complexity and potential liability to the clinical trial arena. Certain HIPAA provisions deal with patient information gathered in connection with research, requiring specific disclosures to patients regarding the use of their information in the course of the trial. HIPAA also requires certain authorizations from the patient before his or her information may be used or disclosed for research purposes. Failure to comply with these requirements can result not only in liability for improper disclosure, but also in an inability to use the data collected. While pre-compliance (April 14, 2003) consents generally are "grandfathered," post-compliance consents must meet FDA, Common Rule, and HIPAA requirements.

At this time, the benefits of clinical trials far outweigh their costs and potential liabilities. Cancer centers should be encouraged to participate in trials to advance medical discovery, but should also take steps to reduce the chance of liability. Each institution should carefully review all trial protocols that are proposed and ensure that its IRB has sufficient time and expertise to review them. All patient consent forms should be updated to reflect the HIPAA requirements so information gathered in a trial can be used for its intended purposes and disclosed as necessary. State law requirements, such as rules relating to testing, the destruction of genetic information, and requirements for informed consent, should also be reviewed. Additionally, the institution should establish clear policies regarding conflicts of interest and the reporting of adverse events.

For information on clinical trials, including informed consents, risks, and other considerations, log onto *www.clinicaltrials.gov*, a web site sponsored by the National Institutes of Health.

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