

"Confidentiality in Clinical Trials: Understand your Liability"

FDAnews, October 2006, 106 pages, \$295.00

Review by Norman M. Goldfarb

"Confidentiality in Clinical Trials: Understand your Liability" provides a thoughtful and clearly-written 17-page exposition of the issues, laws, risks and best practices relating to disclosures of confidential information about clinical trials. The balance of the report consists mainly of the relevant laws, regulations and congressional documents. This report is useful for clinical research sponsors, sites, CROs, IRBs and any other organization with access to confidential information about clinical trials.

The spectacular insider-trading scandal at ImClone that started in 2002 apparently did not put the fear of God into potential miscreants. On August 7, 2005, the Seattle Times published an expose' of numerous leaks of confidential information about clinical trials that may have been used for insider trading. Some of the leaks were careless errors; others were solicited in organized programs by stock market investors and securities firms. Regardless of the cause, if research sites and other organizations privy to proprietary information cannot hold it in confidence, the entire clinical research industry will suffer.

Insider trading occurs "when those who are privileged to have confidential information about important events or circumstances use that information to their special advantage to reap profits in the stock market, usually to the detriment of the source of the information and to traders in the market who do not have the benefit of that information."

Early information about a clinical trial is extremely valuable. A friendly physician, departmental secretary, or IRB member can come into possession of information worth hundreds of millions of dollars. Everyone in the chain of information is potentially liable for damages far exceeding their personal net worth, not to mention the liability of the organization that employs them. The person casually asking about a clinical trial may not be asking out of simple curiosity; according to the report, ten percent of physicians in the U.S. have made themselves available to serve as consultants to the financial industry.

Clinical research sponsors and sites can limit the risk of improper disclosures through education, conflict-of-interest policies, and legal agreements. Confidentiality and clinical trial agreements, unfortunately, have limited value in preventing disclosures. Because every sponsor has a different template, it is unrealistic to expect site personnel to understand the nuances. Since it is impossible to remember the specifics of each agreement, many site personnel do not bother reading them at all. Fortunately, this report is now available to form the foundation of an educational program.

The report is available at <http://www.fdanews.com/>

Reviewer

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