JOURNAL OF CLINICAL RESEARCH BEST PRACTICES

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Letter to the Editor of the New England Journal of Medicine

By Norman M. Goldfarb

The New England Journal of Medicine recently printed an article about clinical trial agreements:

Academic Medical Centers' Standards for Clinical-Trial Agreements with Industry

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ABSTRACT

Background. Although industry sponsors provide approximately 70 percent of the funding for clinical drug trials in the United States, little is known about the legal agreements that exist between industry sponsors and academic investigators. We studied institutional standards regarding contractual provisions that restrict investigators' control over trials.

Methods. We used a structured, cross-sectional mail survey of medical-school research administrators responsible for negotiating clinical-trial agreements with industry sponsors.

Results. Of 122 institutions approached, 107 participated. There was a high degree of consensus among administrators about the acceptability of several contractual provisions relating to publications. For example, more than 85 percent reported that their office would not approve provisions giving industry sponsors the authority to revise manuscripts or decide whether results should be published. There was considerable disagreement about the acceptability of provisions allowing the sponsor to insert its own statistical analyses in manuscripts (24 percent allowed them, 47 percent disallowed them, and 29 percent were not sure whether they should allow them), draft the manuscript (50 percent allowed it, 40 percent disallowed it, and 11 percent were not sure whether they should allow it), and prohibit investigators from sharing data with third parties after the trial is over (41 percent allowed it, 34 percent disallowed it, and 24 percent were not sure whether they should allow it). Disputes were common after the agreements had been signed and most frequently centered on payment (75 percent of administrators reported at least one such dispute in the previous year), intellectual property (30 percent), and control of or access to data (17 percent).

Conclusions. Standards for certain restrictive provisions in clinical-trial agreements with industry sponsors vary considerably among academic medical centers. Greater sharing of information about legal relationships with industry sponsors is desirable in order to build consensus about appropriate standards.

Letter to the Editor

The following letter to the editor of the New England Journal of Medicine was not accepted for publication, but may be of interest to readers of the Journal of Clinical Research Best Practices.

The recent article, "Academic Medical Centers' Standards for Clinical-Trial Agreements with Industry" is an excellent contribution to a very important topic. The negotiation of clinical trial agreements (CTAs) puts academic medical centers at a severe disadvantage versus community-based sites that are not concerned about intellectual property and publications. Their share of the industry-sponsored clinical research market has now declined to 26%.[1] All parties, however, share concerns about payment, subject injury and indemnification terms.

Many institutions factor the likelihood of an invention or publication into their negotiating strategy. Perhaps a follow-up study could categorize the results by phase of trial and whether they are investigator-initiated.

“Contract and budget negotiation and approval” is now the number-one source of delay in clinical trials.[2] MAGI, the Model Agreement Group Initiative, is finalizing a flexible, multiple-choice model CTA with accompanying commentary to streamline the process and help all parties understand the issues at play.[3] MAGI has members from many of the leading academic medical centers, as well as the largest pharmaceutical companies and contract research organizations (CROs).[4]

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References:

1. “Evolution of the Study Contract Market”, Daniel McDonald, Indiana Health Industry Forum Annual Conference, May 2005
2. U.S. Site Survey, The CenterWatch Monthly, May 2002
3. Standardizing CTAs: International Efforts", Norman M. Goldfarb, Applied Clinical Trials, February 2005
4. MAGI Members are from… (Accessed June 30, 2005, at http://www.firstclinical.com/magi/MAGI%20Members.pdf)