

Clinical Trial Injuries

Will Your Client Lose His/Her Medical Practice?

Part Two of a Two-Part Article

By Norman M. Goldfarb

Clinical trial agreements can almost always be negotiated. Most part-time investigators, however, do not have the necessary legal expertise or time to interpret the agreement and conduct an effective negotiation. Proper legal representation at present requires an attorney who is expert in this very specialized field. Because sponsor negotiators often have huge backlogs of contracts in process, and over half of part-time investigators do not negotiate (or even read) the clinical trial agreement, an investigator who opens a negotiation may never emerge from the queue.

A NEW SYSTEM

A new system to help negotiators is now in the works. Over 200 sites, sponsors, contract research organizations (CROs), and site management organizations (SMOs) have joined together in MAGI, the Model Agreement Group Initiative. MAGI is developing a very flexible “multiple-choice” model clinical trial agreement to streamline negotiations in the U.S. and internationally. MAGI’s growing membership includes representatives from over two-thirds of *U.S. News & World Report’s* Top-50 Research Medical Schools and Honor Roll hospitals, many of the largest SMOs, the four largest CROs (eight of the top nine), two of the top four biotechs, and a number of smaller and mid-sized pharmaceutical companies.

One of MAGI’s objectives is to educate both parties in the negotiation. Its model clinical trial agreement will therefore be accompanied by commentary, explaining the implications of the contract text. Attorneys who may not specialize in these types of contracts will be able to gain valuable insights, and even negotiators without legal expertise will become much more effective.

MAGI members help draft one of 90 sections of the model agreement. Membership is free and there is no obligation to use the resulting model agreement. MAGI co-manages a biannual educational conference, offers professional Clinical Research Contract Professional (CRCP) certification, and publishes a semi-weekly e-newsletter. More information is available at www.firstclinical.com/magi.

GOOD NEWS FOR CLINICAL INVESTIGATORS

It’s best to be prepared for the worst, but the news is not all bad for clinical investigators. To start with, only a small percentage of the over 2.3 million subjects who take part in studies each year in the U.S. are injured during clinical trials. Only a small percentage of those injured have a legitimate cause of action against the investigator or sponsor. Most legitimate causes of action (and many that are not legitimate) are resolved quickly and economically. It’s a cost of doing business for sponsors, and they generally prefer to avoid publicity.

The number of cases that reach trial will probably increase over time, but today, very few do. Of these, defendants have a good batting average in winning. The best litigation is, of course, litigation that never occurs. Research hospitals have the expertise and financial resources to protect themselves. In addition to taking part in the MAGI project or something similar, independent physicians can take several steps to protect themselves from the risk of liability claims by injured study subjects:

- Do not conduct a trial that is likely to be associated with serious-subject medical problems. In other words, stay away from acute diseases and fragile populations.
- Ensure that investigators and study coordinators understand and comply with the protocol and Good Clinical Practice. Understand your medical malpractice insurance — obtain clarification from your carrier if the policy is ambiguous — and secure adequate coverage. A claim by a sponsor against a small site for financial damages is unlikely, but consider obtaining an error-and-omissions liability policy to protect against this type of risk. Architects, for example, buy errors-and-omissions insurance to protect them if a building they design collapses.

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- Weigh the risks of the trial vs. the potential rewards. Cross-indemnification may be justified if the study

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budget is generous and the chance of subject injury is negligible.

- Read and understand the indemnification, insurance and subject injury sections of the clinical trial agreement. Do not conduct a trial if the sponsor is unwilling to accept your contract requirements. Consult with a qualified attorney, as appropriate.
- Do not enroll high-risk study subjects, even in low-risk studies.
- Do not ignore injured subjects in

the hope that they will go away.

- Terminate the trial at your site if, in your professional judgment, the risk to the subjects outweighs the potential benefits.



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