

of his surgery.” The court further held that under these “particular facts,” a hospital, as well as a physician, may be held liable for claims arising from the lack of informed consent.

## WHAT TO CONSIDER WITH CLINICAL RESEARCH LIABILITY COVERAGE

It’s important to note that, regardless of fault or any wrongdoing, a plaintiff may sue an organization engaged in clinical research, and in doing so the defendant organization would incur costs for defense of the suit. Essentially, purchasing clinical research liability insurance transfers risk to an insurance company. And, if a covered incident were to arise, the insurance company would be obligated to provide defense of the claim under the terms of the policy.

From a coverage perspective, there are several key things an organization should understand before they purchase a policy. Following are various coverage options that pertain to clinical research. The wording of these options is general and the specific wording and coverage varies by underwriting company, underwriting expertise, and experience.

### A. Clinical Research Professional Liability Coverage (E&O – Financial Loss)

With E&O coverage, the insurer agrees to pay on behalf of the insured, subject to the limit of liability, loss and defense expenses in excess of the retention or deductible, which the insured becomes legally obligated to pay as a result of a claim for an act, error or omission by an insured for the rendering of or failure to render research-related services.

It is important for an organization to carefully review the definitions of terms used in the policy, especially for research-related services. Covered services should include, obviously, those that the organization is engaged in providing.

### B. Medical Services Professional Liability Coverage (Medical Malpractice)

The insurer will pay on behalf of the insured, subject to the limit of liability, loss and defense expenses in excess of the retention or deductible which the insured becomes legally

obligated to pay as a result of a claim for an act, error or omission by an insured’s rendering of or failure to render research-related medical services (i.e., a bodily injury claim). Again, it is important to understand the definitions to be sure research-related medical services performed by the organization are covered under the policy.

### C. Administrative Proceedings Defense Coverage

The insurer will pay on behalf of the insured, subject to the limit of liability and in excess of the retention, defense expenses incurred by the insured in connection with an administrative proceeding for an act, error or omission by an insured.

This is a coverage part that may respond if the FDA were to audit a clinical research site and the site had to retain legal counsel to respond to those citations.

### D. Supplemental Payments - Crisis Management Coverage

The insurer will pay on behalf of the insured entity, subject to the limit of liability, crisis management expenses incurred in connection with crisis management events.

The coverage may respond to a clinical research entity that, as a result of a trial, was targeted by a group demonstrating against some aspect of clinical research. The research entity may want to engage the services of a media/public relations service provider to address the allegations brought by the demonstrators.

For more information about Darwin’s clinical research liability insurance, visit [www.darwinpro.com](http://www.darwinpro.com) or contact Gary Leavy at 860 284 1434 / [glevy@darwinpro.com](mailto:glevy@darwinpro.com).

<sup>1</sup>Karin Morin, LLM, et al., *Managing Conflicts of Interest in the Conduct of Clinical Trials*, *Journal of the American Medical Association*, Vol. 287, No. 1 (Jan. 2, 2002).

<sup>2</sup>Debbie Goldberg, *Artificial Heart Implant Leads to Suit Over Consent Process: Recipient’s Widow Says She and Her Husband Were Misinformed and Misled on Risks, Benefits*, *The Washington Post*, November 30, 2002.

<sup>3</sup>Duff Wilson and David Heath, *Uninformed Consent: Patients Never Knew the Full Danger of the Trials They Staked Their Lives On*, *Seattle Times*, March 2001.

<sup>4</sup>Deborah Nelson and Rick Weiss, *Penn Researchers Sued in Gene Therapy Death*, *Washington Post*, September 19, 2000.



## FROM CLINICAL TRIAL TO LEGAL TRIAL CLINICAL RESEARCH EXPOSURES NECESSITATE PROFESSIONAL LIABILITY INSURANCE COVERAGE

By Gary Leavy

The clinical research industry is experiencing rapid growth. Most significantly, clinical research, where once confined to teaching hospitals, has expanded well beyond medical academia. This expansion has resulted in the formation of numerous types of independent entities specializing in clinical research, as well as an increase in individual independent research contractors.

Let’s start with a quick overview of some of the organizations engaged in various aspects of clinical research today.

*Contract research organizations*, also known as CROs are entities contracted by a biotech or pharmaceutical company (sponsor), to carry out their clinical research activities for a particular drug or medical device.

*Institutional or independent review boards (IRBs)* are specially-constituted review bodies established or designated to protect the welfare of human subjects recruited to participate in biomedical or behavioral research. An IRB, which is usually composed of both physicians and lay people, is charged with examining the study’s protocol to ensure that the patient’s rights are protected, and that the study does not present an undue or unnecessary risk to the patient.

*Site management organizations (SMOs)* are in the business of streamlining functions that typically create bottlenecks in clinical trials, such as patient recruitment, investigator and site selection, and study initiation. Typically, they contract their services to either the sponsor or to a CRO. The SMO’s primary clients, in the current environment, are either drug study sponsors or CROs that are seeking to control fixed costs.

### WHERE THE LIABILITY IS

Clinical research professional liability insurance has emerged as a critical coverage for today’s clinical research services firms. This is true, in large part, because any firm in today’s litigious society that provides advice or other services as its core product is subject to threat of a lawsuit. Specifically, an organization engaged in any aspect of clinical research is subject to the threat of claims alleging misstatements, claims challenging the veracity of its information, or to allegations that a breach in protocol by staff members has caused a client to suffer a *financial loss* or a research subject to suffer *bodily injury*.

The costs of a clinical trial are borne by the sponsor—the owner of the product who is responsible for manufacturing a drug or device. The sponsor, in turn, hires independent professionals and/or organizations (e.g., CROs) to manage the research trial process itself. Depending upon the type

of entity, CROs may offer services across all aspects of the research process, including:

- recruiting study subjects
- dosing patients with a study drug (or placebo)
- functioning as a trial site
- contracting with a trial site
- developing research protocols
- contracting with or using employed research professionals to manage the research and collection and management of the trial data for reporting back to the sponsor.

These entities have an errors and omissions (E&O) exposure related to the collection and management of research data, and they may also have a medical malpractice exposure if they employ or contract with the research professionals who have direct patient contact or manage the trial. It should be noted that the bodily injury exposure is mitigated by indemnification from the sponsor for injury due to the drug or device.

### WHY THESE FIRMS NEED CLINICAL RESEARCH LIABILITY INSURANCE

Virtually any firm that provides advice or other services as its core product faces an increased threat of claims alleging errors and omissions in the performance of its duties. As a result, there is a greater demand for clinical research professional liability insurance. Some key factors that are driving an increase in demand for clinical research liability insurance include:

- *Investment in research and development by the top 20 pharmaceutical companies has more than doubled in the past 7 years.* In contrast, revenues are expected to grow by only 7% per annum for the coming years. Therefore, companies will need to generate more than \$25 billion in sales to maintain current levels of profitability, which will require industry leaders to launch between 24 and 34 new drugs per year.<sup>1</sup>

- *The shift from a manufacturing based economy to one dominated by service sector businesses.* In a manufacturing based economy, liability exposure generally arises from product liabilities. As economies shift to include more service-oriented business,





as we are experiencing in the U.S., the greater the need for professional liability insurance. This has a direct impact on the clinical research industry where drug and device manufacturers may incur product liability, and their contracted research service providers may incur professional liability.

- A growing number of professional service firms are required to provide proof of insurance in order to land a contract. This is especially true in situations where consultants are working on a contract basis with clients. It is standard operating procedure at a growing number of companies to require proof of liability insurance before they work with an outside consultant or service provider.

- The growing importance/pressure of providing additional advice and services, than in the past. To remain competitive, many professional services firms are offering additional services and advice. This expansion of services is changing the core business functions of professions that have long been restricted by traditional boundaries. A good example is when a CRO expands beyond providing data management services into a new practice area that may include direct patient contact. New services bring with them a broader potential for professional liability claims because the newer practice area or service may pose unfamiliar or hidden risks.

- Clinical trial litigation trends. It is a reality that there are an increasing number of clinical trials conducted in the United States. Lawsuits are regularly brought in the U.S. and in foreign venues where clinical trials are being conducted. This is giving rise to plaintiff law firms setting up life science practices and lawyers crafting new and creative causes of action based on clinical trials. Courts have even become much more willing to entertain causes of action on clinical trials.

## CLINICAL RESEARCH LIABILITY EXPOSURES

IRBs, SMOs, CROs, and research sites give us some insight into the exposures faced by clinical research service providers in today's marketplace. IRBs are at risk of approving improperly developed protocols or inappropriate/misleading consent forms. This presents an exposure to a financial loss due to potential trial delay, which may then result in a missed/lost milestone payment. A vicarious medical malpractice/bodily injury exposure also exists due to an improperly developed protocol approved by the IRB, which results in an injury to a trial subject.

SMOs have both E&O (handling data) and medical malpractice (direct patient contact) exposures. The level of exposure will depend upon the operational model employed by the SMO, the number of sites managed by the SMO at any one time, and the obligations/services assumed by contract. Operational models employed by SMOs are as follows:

- Owned facilities with employed investigators
- Outsourced clinical trials under supervision of contracted physicians
- Brokered services
- Affiliated with an investigator-owned network

The degree of exposure a CRO faces depends largely on whether or not there is a medical malpractice exposure that has been assumed by contract. Following is a list of services that would limit the exposure to financial loss or necessitate coverage for both the financial loss and bodily injury.

- E&O exposure only when a CRO:
  - Provides service to entities other than the sponsor
  - Provides service directly to the sponsor
  - Evaluates (and or monitors) reports and prepares materials to be submitted to the FDA
  - Employs clinical research subcontractors for the purpose of monitoring, data management, etc.
  - Manages multiple sites (data management)
- E&O and Medical Malpractice exposure when a CRO:
  - Manages the trial
  - Develops the trial protocol and consent forms
  - Has direct patient contact (dosing patients with study drug, drawing blood, etc.)
  - Develops products
  - Offers central laboratory services
  - Employs coordinators (CRCs)
  - Recruits patients

## CLINICAL RESEARCH CLAIMS ENVIRONMENT

As previously stated, the clinical research industry is experiencing rapid growth and has grown beyond the traditional boundaries, historically confined to teaching hospitals. This expansion has resulted in the formation of numerous types of independent entities specializing in clinical research, as well as an increase in individual independent research contractors. The highly competitive nature of the industry and the increasing number of research organizations has led to an increase in claims activity. *It is important to note that a clinical research organization or contractor just has to be named in a claim to incur costly defense expenses.*

Consider the following lawsuits that resulted in the deaths of research subjects.

1. *Quinn v. Abiomed Inc.*<sup>2</sup> – Widow of the now-deceased recipient of an artificial heart is suing the hospital and manufacturer of the heart alleging that the information that they received prior to his implantation was insufficient to properly inform them of the ramifications of their decision to participate in the experimental implantation.

2. *Wright v. the Fred Hutchinson Research Center*<sup>3</sup> – Wright and several other patients suffering from leukemia died after participating in bone marrow transplant trials at the Fred Hutchinson Research Center in Seattle, Washington.

3. *Gelsinger v. University of Pennsylvania*<sup>4</sup> – Gelsinger died during a gene therapy trial at the University of Pennsylvania, raising allegations that he and his parents were not provided with sufficient information regarding the risks of liver damage.

Typically, doctors—not hospitals—have the duty to obtain informed consent. However, cases involving “clinical trials” illustrate an exception to this general rule. In the case *Lenahan v. University of Chicago*, 2004 WL 635570 (1st Dist., March 31), the Illinois Appellate Court, reversing a ruling by the Cook County Circuit Court, decided that a malpractice complaint adequately alleged that a hospital running a clinical trial assumed and breached the obligation to get valid consent from a cancer patient.

Assuming that the facts alleged in the complaint are true, the reviewing court also concluded that:

- the hospital could be held liable for not adequately supervising a physician; and
- a doctor owed a tort duty to a patient he never personally encountered.

The case of *Kus v. Sherman Hospital*, 268 Ill.App.3d 771 (1995), also points to institutional negligence with informed consent protocol. In *Kus*, a patient who was implanted with experimental intraocular lenses brought suit against Sher-

man Hospital and a physician for failure to obtain informed consent. The patient alleged that the consent form that he signed had been modified from the FDA-approved form and did not inform the patient that the lens was experimental and being evaluated for safety and effectiveness.

“The appellate court noted the general rule that physicians, not hospitals, have the duty to obtain informed consent from their patients. The rationale for this rule is that the physician has the knowledge and training necessary to advise each patient of the risks, whereas the hospital does not know the patient's medical history or the details of the particular surgery to be performed.

However, the court further noted that intraocular lens implants were subject to specific FDA regulations regarding informed consent, and that pursuant thereto Sherman Hospital had established an IRB to assure that a legally effective informed consent was obtained.

“The court held that “[w]hile we agree that generally a hospital is not in the best position to inform a patient of risks, here it is clear that Sherman Hospital undertook the responsibility to inform the plaintiff of the experimental nature

