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Clinical Trial Exposures: A Guide for Academic Institutions

Conducting clinical trials in an academic institution raises some complex coverage issues. Clinical testing liability scenarios may vary depending upon the following factors, among others:

- Whether the institution is the trial sponsor or has ownership of the test articles being investigated.[1]
- Whether the academic institution is a public or private enterprise.[2]
- Whether the principal investigator (PI) engaged in the trial is a contractor or employee.

Risk managers at academic institutions involved in human clinical trials understand the need for a risk transfer program to address organizational liability. However, it is equally important to identify when additional insurance is and is not required. Failure to obtain certain types of coverage leaves the institution exposed, while acquiring unnecessary insurance is wasteful for the insured and may result in clashing issues for the insurer.

Identifying gaps in coverage requires a diligent review of the current insurance program and a thorough understanding of the specific research activities in which the institution is engaged. This article will focus on the four areas of risk most likely to require additional or enhanced coverage for academic institutions:

- Clinical trial-related product liability
- General liability (GL)
- Medical professional liability (MPL)
- Clinical trial-related professional liability (i.e., errors & omissions)[3]

A hypothetical liability scenario is included to indicate how insurance coverage questions may play out in actual clinical trial situations.

GENERAL LIABILITY

In its most basic form, GL covers an occurrence where the institution is legally liable for bodily injury and property damage to a third party. Under most circumstances, a sponsor's GL policy will exclude medical professional services as well as injuries to clinical trial subjects. However, bodily injuries from an institution's own products may not necessarily be excluded. Because clinical trial-related exclusions are manually added and can be overlooked, policy wording must be closely examined. Whether due to simple oversight by the insurer or because the institution's ordinary course of business does not include clinical trials, there is a *possibility* of coverage under its GL policy.

The academic institution also may be protected from loss by strong indemnification language within the clinical trial agreement (CTA). However, indemnification disputes can arise when bodily injury allegations touch on both protocol and medical negligence. Typically, the sponsor of a clinical trial is responsible for the protocol, while the investigator is responsible for execution. However, these protections, which differ from the special relationship between insurer and insured, may not be effective under all circumstances.[4]

In addition, institutions may enjoy less contractual protection when involved in a PI-initiated trial where the test article is already on the market or owned by the institution, and the sponsor (i.e., the industry sponsor) is acting merely in a funding capacity. In this situation, the institution must carefully assess its exposures and determine whether it is safe to rely upon self-funding, or whether insurance coverage is necessary to help offset the risk.

1 Investigator-initiated studies (also referred to as principal investigator- or PI-initiated trials) are trials initiated by the investigator (i.e., the sponsor-investigator). The test article in a PI-initiated study may be owned by a university and may or may not be already on the market. The sponsor-investigator will typically seek various resources from the industry-sponsor, such as funding, a supply of the test article, controls and/or expertise in regard to regulatory filings. When the drug/device is owned and controlled by a pharmaceutical or medical device company, which also funds the study and designs the research plan and protocol, the study is referred to as a sponsor-initiated trial.

2 *Sovereign immunity*, the legal concept that one cannot bring suit against the state without its consent, is a factor in assessing the liability exposure of public institutions such as state universities. Sovereign immunity can be absolute or qualified depending upon state law.

3 In this context, "professional liability" refers to errors & omissions consequential financial loss coverage. Professional liability coverage for bodily injuries is referred to as medical professional liability or medical malpractice insurance.

4 Indemnification obligations are contractual rights that may be disputed or not enforced. By contrast, statutes impose special performance standards on insurance companies and offer plaintiff-insureds more possibilities regarding type and amount of damages.

The following limitations should be considered when assessing the breadth of coverage of the institution's GL policy:

- If the policy includes products-completed operations coverage, bodily injury from institutionally owned or operated life science products may be excluded by endorsement.
- There may be ambiguity (rather than an affirmative exclusion) regarding bodily injury claims involving the institution's products.
- Some bodily injury coverage may exist, while claims involving products are specifically excluded in the context of clinical trials.
- Specific exclusions may exist based upon the phase of the trial, the type of product or even the population on which the product is being tested.

Other exclusions or ambiguities may exist within the institution's GL policy, such as advertising and personal injury coverage for claims stemming from clinical trials.

PRODUCT LIABILITY

A broker may recommend to the risk manager of an institution engaged in human trials that it purchase a separate product liability policy to minimize the risk of claims alleging bodily injury to study participants. However, such additional coverage may be unnecessary or even counterproductive unless the broker and risk manager understand the type of trials being conducted by the research center and the extent of coverage granted by the GL policy.

A separate product liability policy could be an asset under certain circumstances, as suggested by the following scenarios:

- The institution exerts primary ownership and/or control of the test article (e.g., in a PI-initiated trial).
- The CTA with the sponsor does not fully indemnify the institution.
- The institution's GL policy excludes product-related bodily injury.
- Clinical trial activities are excluded or not covered based upon policy language concerning the types of trials, subject populations or products.

If any or all of these conditions exist, a specialty product liability policy may be worth considering to provide coverage for the institution against possible bodily injury claims.

MEDICAL PROFESSIONAL LIABILITY

The risk transfer programs of academic institutions involved in clinical trials should address the liability associated with bodily injury due to institutional medical negligence. Effective risk management involves identifying and responding to the type of trial undertaken, the employment status of the PI and the sponsor arrangement.

When bodily injury claims are asserted against the institution, an impasse may ensue between sponsor and institution over the question of whether the sponsor's protocol/product or institutional medical negligence is responsible for the injury and consequent claim. The potential consequences of any causation-related ambiguity can be severe.

Unless the PI employee or contractor has coverage for medical services at the clinical site conducting clinical trials, defense costs and/or damages may be borne by the institution. Also, as plaintiff attorneys may allege that both parties are at fault, it is imperative for the risk manager to understand the extent of the organization's clinical investigation-related medical professional liability (MPL) coverage, as well as the scope of coverage pertaining to PIs acting as contractors rather than full-time employees. Finally, as MPL policies may treat varying types of clinical risks and trials differently, it is important to stay apprised of both the responsibilities assumed in the CTA and the type of research that the institution is undertaking in order to ensure that current trials are covered under the policy.

The institution's exposure in a sponsor-initiated trial may be reduced by contractual provision in the CTA, as such indemnification language is often broader in scope.[5] If a claim arises, it is "filtered" through the CTA and any remaining exposure falls upon the institution. In a PI-initiated trial, the CTA may not cover the research center. This creates more risk exposure. In either case, the institution may not be indemnified for injuries stemming from its own negligence. A sound MPL program will respond to cases of obvious medical error or negligence, or if there is a dispute between a sponsor and research institution over the cause of bodily injury in a clinical trial.

When determining whether to acquire MPL coverage for employees, consider the following points:

- MPL coverage should apply to clinical trials when subjects are receiving clinical treatment outside of protocol requirements.
- MPL, GL and product liability should be evaluated *together* to spot potential gaps in coverage.

5 Note that whether the trial is initiated by the sponsor or PI, the plaintiff(s) will typically name many parties in the complaint with the sponsor and institution at the top of the list.

- Policies are available that offer combined exposure for products and MPL.
- The medical malpractice standard of care is different when treating a patient than when conducting research on a subject.
- To ensure that selected insurance solutions provide adequate coverage, attention should be paid to the specific type of product being tested, the population of subjects involved in the studies, the phase of the investigation and the ownership of the test articles being investigated.

Before retaining contractors in human clinical research trials, verify the following:

- Contractors' certificate of insurance includes coverage for bodily injury and professional liability resulting from clinical trials.
- Contractors' policies have adequate limits and contain language making their liability coverage primary with the institution named as an additional insured.
- The institution's privilege endorsement includes MPL coverage for clinical trial activities.

PROFESSIONAL LIABILITY/ERRORS & OMISSIONS

In addition to bodily injury claims (whether arising from product defect or medical malpractice), institutions carry a significant exposure for financial losses incurred by trial sponsors, contract research organizations (CROs) and other third parties. By purchasing a professional liability/errors & omissions insurance policy, institutions can better manage consequential financial damages stemming from such third-party losses. This type of coverage may apply to indemnity payments and legal costs involved in defending against these allegations. Without this protection, the institution bears a greater level of risk.

While a separate product liability policy to cover human trials may not always be appropriate, the same is not true for professional liability/E&O coverage. Typically, institutions engaged in clinical trials benefit from a professional liability policy and should seriously consider this coverage to mitigate the consequences of financial losses experienced by the study sponsor due to failure to produce usable data or other causes. When consequent lawsuits occur, it is the professional liability policy that responds to financial losses suffered by third parties who in turn seek recovery from the policyholder. It has become common for trial sponsors to require institutions to maintain this type of coverage, because the frequency and severity of these losses are growing.[6]

If a trial sponsor sues a research center, alleging that its negligence contributed to the study's failure, the institution's professional liability policy may pay indemnity costs or at least defense-related expenses. In fact, sponsors frequently require research institutions, sites and CROs to maintain E&O coverage. Specialized insurance products used in combination with a product liability policy may assist in mitigating such losses.

Professional liability/errors & omissions insurance should be considered under the following circumstances:

- The institution engaged in clinical trials is doing work for others under a CTA agreement and generating data upon which the sponsor will rely.
- The institution is contractually obligated to carry professional liability coverage.
- The CTA lacks limitation of liability provisions, which may reduce institutional exposure.[7]

Clinical trial contracts are often nuanced and complex. Hence, it is advisable to scrutinize such contracts – especially in terms of the roles, responsibilities and risk allocations of each party – in order to avoid false assumptions and oversimplifications. Moreover, by evaluating clinical trial professional, medical professional, general and product liability policies together, one can create an effective insurance program that minimizes coverage gaps and significantly mitigates exposures.

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6 A party's negotiating leverage and industry practice will always be a factor in the decision whether or not to purchase insurance. Today, it is commonplace for sponsors to ask institutions to purchase errors & omissions, and institutions, sites and CROs are actively obtaining this type of coverage.

7 Although, as previously noted, such provisions may have limited utility if causality is disputed (thus incurring additional legal costs) or if the provision is unenforceable based upon the facts at hand.

Sidebar: A Clinical Trial Liability Scenario

The scenario presented below is intended to illustrate important concepts in clinical trial-related liability. Note that coverage may depend upon the following variables:

- *Whether the protocol was strictly followed.*
- *Whether patients were present near test subjects at the trial site.*
- *The scope of coverage under the PI/institution medical professional liability policy.*
- *The employment status of the PI.*

In this hypothetical scenario, the PI follows the protocol while administering the test article. Nevertheless, a subject is injured and sues everyone involved including the sponsor, the PI and the institution. In this relatively simple example, the institution would likely be covered by the sponsor's product liability policy if it is named as an additional insured or through existing contractual indemnity requirements. (For maximum security, the institution should request a certificate of insurance confirming coverage, limits and terms.)

Real-life claim situations tend to be more complex. For example, let us assume that a nearby patient who is not involved in the trial asks the PI to examine some type of abnormality (a "lump") while the PI is administering the test article on a trial subject. The PI ignores her request and instead focuses on the subject while following the trial protocol. Later, the patient alleges that her ailment was exacerbated by the PI's unwillingness to take action. The patient then sues both the PI and the institution for injuries resulting from the failure to examine/treat. Under these circumstances, the sponsor's product liability policy probably would not cover the PI/institution, because the alleged bodily injury did not involve the sponsor's test article, trial or subject. However, depending upon the nature of the claim and the allegation, the institution's medical professional liability insurance may respond.

Now consider an otherwise similar scenario, in which the PI steps away from the subject to look at the patient's lump. The PI's distraction and consequent deviation from protocol results in an injury to the subject. The subject then sues the PI, the institution and the sponsor, and the institution is uncertain as to whether possible damages will be covered and if there is a remedy for legal costs. The sponsor's product liability/clinical trials policy taken out to cover the investigation may not respond if the PI deviated from the protocol, as this is a common exception to coverage. On the other hand, the institution's MPL policy may *provide coverage,* but this also depends upon other considerations (e.g., the general exclusionary effects of medical malpractice coverage in a clinical trial setting, whether the injured party is a subject or a patient, specific types of trials excluded from coverage, etc.). Whether coverage from either type of policy would respond depends, of course, on what specific allegations were made and what the investigation into the facts reveals.*

There are other factors to consider if the PI is a contractor. For a contractor-PI, it would be prudent to ensure that the privilege endorsement for a particular site/institution includes MPL coverage for the clinical trial activities. As for the institution/clinical site, a certificate confirming proper liability coverage on a primary basis would serve as evidence of insurance.

As with many claim scenarios, whether in the context of a clinical trial or otherwise, coverage will depend upon factual circumstances and the nature of the allegations. One word in the complaint could determine whether a policy will or will not respond to an event.

A fundamental concept in sponsor-initiated clinical trials is that the PI is acting on behalf of the sponsor to carry out the investigation. A sponsor may defend bodily injury allegations against the PI and institution to the extent of determining whether the PI was performing within protocol guidelines, but it would not likely cover damages if it found that the PI was operating outside of these constraints. To the extent that the PI acts in the capacity of a medical doctor treating patients (as opposed to subjects in a clinical trial), then, depending upon the facts of the case, either the institution's or a contractor-PI's MPL policy may respond. To add yet another layer of complexity, there is also the possibility of a blended response, whereby the PI's MPL coverage acts as excess cover above the sponsor's products liability policy.

To reiterate, in every instance insurance coverage will depend upon careful analysis of the facts, allegations and relevant policy provisions. While this article describes various hypothetical scenarios, actual coverage questions and other risk-related topics should be discussed with a knowledgeable insurance professional.

* In medical malpractice policies, it is imperative to understand the definitions of such key terms as *medical services, professional services, patients, subjects, employees, consultants/contractors,* etc.

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