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# Indemnification in Clinical Trial Agreements

**By Michael Powers and Kelly Smith**

Indemnification clauses ("indemnities") in clinical trial agreements (CTAs) between study sponsors and research sites are highly complex. Although they are seldom triggered, when they are triggered, the stakes are high. This article will discuss certain legal aspects of indemnification clauses from both the sponsor and site perspectives in industry-sponsored clinical trials. However, we will not propose language; for that, consult MAGI's Model Clinical Trial Agreement, available at www.magiworld.org/standards.

"Indemnification" is defined as "a duty to make good any loss, damage or liability incurred by another" (Black's Law Dictionary). In other words, indemnification is a guarantee by one party (the Indemnitor) against a loss that another party (the Indemnitee) might suffer to a third party.

## Is Indemnification necessary in your CTA?

As a preliminary matter, the first decision a sponsor or site needs to make is whether an indemnification clause is required and how stringent it should be. The need for indemnification is influenced by the risks involved with the protocol and the subject population involved in the study. The risks in a Phase I first-in-man study might be much higher than in a Phase IV observational study of an FDA-approved drug. The risks involved with a subject population of terminal cancer patients might be much lower than with a subject population of young, active individuals.

Indemnification is worthwhile only if the Indemnitor has the financial strength to stand behind it. In many cases, the coverage afforded by the Indemnitor's insurance policy is thus important. For example, a pharmaceutical company's policy might provide coverage for injuries caused by the experimental medication but exclude coverage for an active control, study procedures, or indirect harms, e.g., to persons other than the study subjects.

Most site insurance policies do not cover a contractually granted indemnity to the sponsor. Moreover, Veterans Administration hospitals[1] and state-owned institutions are generally incapable of granting indemnification because of sovereign immunity statutes that restrict this as a matter of public policy.

Your own insurance policy, perhaps supplemented with a rider, might provide adequate coverage without indemnification. As with many insurance questions, expert advice is worthwhile.

## How broad an indemnity is required?

After performing this risk analysis and determining that indemnification is necessary, the parties must negotiate the scope of the indemnity to be provided. As with any term of the contract, the content and wording matters.

### Scope of harms covered by the indemnification clause

At a minimum, CTA indemnifications must cover bodily injury to the subjects. They can also cover other types of subject injury, e.g., the release of private health information. As mentioned above, the cause of the injury can be stated narrowly or broadly.

The person claiming damages might not be the study subject; it might be someone who incurred "indirect" damages like the subject's spouse or employer, or an innocent bystander injured by a psychotic subject. In another scenario, a competitor to the study sponsor might sue the investigator for publishing study results that are negative for its product. Thus, defining the scope of harm is critical. If there is a particular risk that concerns you, state it explicitly ("including but not limited to X") in your indemnification clause. Obviously, whether the other side is willing to indemnify for this risk depends on the reasonableness of your request and your negotiating leverage.

### Scope of Indemnitees covered by the indemnification clause

The first rule among personal injury lawyers is to sue EVERYONE when a claim occurs. Therefore, it also important for you to know WHO receives protection under the indemnification clause. If the site's principal investigator is not an employee of the institution entering into the CTA, the site should attempt to include "Principal Investigator" in the definition of Indemnitees. If a site provides indemnification to its own vendors (e.g., labs) or non-employee members of its local institutional review board involved in the study, the site should also attempt to include these third parties in the definition of "Indemnitee" to reduce the site's indemnification burden where the Sponsor is also an Indemnitor.

### Linking the loss to the actions or inactions of the Indemnitor and/or Indemnitees

Rarely will an Indemnitor provide indemnification to an Indemnitee without setting out specific limitations. We have already discussed one such limitation above regarding the scope of harms (a.k.a. "loss" or "claim") covered by the indemnification clause.

Another typical indemnification limitation focuses on the respective actions or inactions of the parties. Most commonly, sponsors are reluctant to indemnify sites for harms caused by the site's negligence or intentional misconduct, especially if the site's actions rise to the level of "gross" negligence: an indifference to, and a blatant violation of, a legal duty with respect to the rights of others. In the case of injury caused by site negligence, the sponsor is likely to require "cross indemnification" from the site.

It is common for sponsor-drafted indemnification clauses to void the site's protections if the site incurs any protocol deviation, whether or not the deviation relates to the harm (a.k.a. "all or nothing" indemnification). Sites should therefore insist that this limitation be restricted to actions or inactions of the site that actually cause the harm, as no clinical trial is completely error free. Again, the wording of the indemnification clause matters. For example, "in connection with" has a broader meaning than "directly arising from." Sites should further argue that indemnification be restricted to actions or inactions by the site that rise to the level of negligence or intentional misconduct. Conversely, the sponsor might want to limit its liability under the indemnification clause to harm caused by its own negligence or intentional misconduct. However, if the sponsor or the contract manufacturer hired by the sponsor adulterates the study drug or improperly manufactures a device that causes the harm when administered per the protocol, the sponsor should indemnify the site regardless of whether there was negligence or intentional misconduct by the sponsor itself (a.k.a. "strict liability").

In some cases, both the sponsor and the site are at fault. In this scenario, the parties typically negotiate some ad hoc form of proportionate indemnification (a.k.a. "comparative indemnity") that assesses the respective fault of each party and reduces the indemnification obligations accordingly. By doing this, the parties avoid the draconian all-or-nothing indemnification discussed above. Here again, the wording ("directly arising from," "in

connection with," etc.) in the CTA matters, since it defines the relevant scope and actions of the parties.

## Interactions with other CTA clauses

The indemnification clause does not stand alone in a CTA. In addition to the insurance provisions discussed above, it also interacts with the following clauses:

### Subject injury

The indemnification clause is often confused with the subject injury clause, but they serve very different, albeit related, purposes:

- The subject injury clause explains what happens when a study subject is injured or claims to be injured. Among other things, it sets forth the parties' agreement as to what constitutes a "study-related injury" and who — site, sponsor or neither — is responsible for the cost of treatment. For example, if a subject is injured by an X-ray scan that is useful for the study but would have been administered anyway as standard of care, is that a study-related injury and does the sponsor have any obligation for the cost of treatment?
- The indemnification clause explains whether one party is responsible for covering the liability of the other party to a third party that claims damages. For example, an injured study subject might sue the site for a faulty study drug or sue the sponsor for a negligent procedure by the site.

Depending on the circumstances, one, both or neither clause might be triggered.

### Limitation of liability

A limitation of liability ("LOL") clause is designed to cap liability damages between the parties. Typically the LOL clause will exclude one party's liability to the other party for indirect, consequential or special damages. Although the indemnification clause addresses claims by third parties (not the parties to the contract), the site and sponsor should make clear in the CTA whether damages arising from the indemnification clause are intended or not intended to be covered by this damages cap.

### Warranties

A warranty is a guarantee or promise that provides assurance by one party to another that certain facts or conditions are true or will happen. By definition, a warranty survives beyond the expiration or termination of the CTA. If a party is unwilling to provide indemnification, warranties can be used as an alternative to create a breach of contract claim if the promised condition does not occur or the promised fact turns out to be false. For example, clinical trial agreements typically include the sponsor's warranty that the study drug or device has been manufactured correctly.

### Survival

The survival clause addresses which sections of the CTA survive expiration or termination of the agreement**.** Since the statute of limitations in most jurisdictions allows a plaintiff to bring a claim a year or more after an injury has occurred, it is very possible that the parties to the CTA will not learn about a third-party claim or lawsuit until after the CTA term has ended. Therefore, it is critical for CTA Indemnitees that the indemnification clause be included in the survival clause of the CTA.

 

**Other indemnification key points**

Some sites that could indemnify sponsors are unwilling to do so, no matter how deficient their actions.[2] In such cases, sponsors may accept the site's position or argue for a clause in which the site at least accepts responsibility for its negligent actions.

Text that appears innocuous can have significant implications in indemnification clauses. In legal contracts, defined terms are capitalized. So, for example, if "Third Party" is defined in the CTA as "an injured study subject," it, by definition, excludes other third parties that would naturally be included had the same term been used in the CTA without capitalization.

If the CTA is between a site and the sponsor's contract research organization (CRO), it typically will not include an indemnification clause, since the sponsor is not a party to the CTA and CROs normally do not indemnify sites. The solution is for the site to obtain a letter of indemnification ("LOI") from the sponsor that may or may not include cross indemnification from the site. If the LOI includes cross indemnification, both the sponsor and the site will sign the LOI. Sites should require that the LOI be attached as an exhibit to the CRO CTA to make clear that the site's clinical trial services for the CRO are conditioned upon this indemnification being received from the sponsor.

Major concerns related to indemnification are the cost and control of litigation. Subject injury litigation can be very expensive, even in a successful defense. Since the Indemnitor carries the risk, it is most concerned with limiting it. Therefore, indemnification normally gives the Indemnitor control over the litigation and any settlement. However, the Indemnitee (e.g., a physician concerned about accepting responsibility and its ramifications for his or her practice and medical malpractice coverage) might want to take control of the litigation, but would typically have to waive the Indemnitor's obligation to indemnify, at least to some extent. In addition, indemnification clauses normally require the Indemnitee to notify the Indemnitor promptly, should it learn of an actual or even possible claim, since a quick response often forestalls costly and time-consuming litigation.

**Conclusion**

A CTA drafted by a sponsor might include relatively limited sponsor-to-site indemnification and relatively broad site-to-sponsor indemnification. Obviously, the site would prefer the opposite arrangement. In theory, the parties should be able to agree on compromise language that meets the needs of both parties. Legal advisors naturally want to protect their clients against all risks, but a CTA is a *business* contract, so the business risks and rewards must be considered. As discussed above, both parties should consider the likelihood and consequences of various risks and focus on those of most concern. Taking a hardline position on unimportant risks might not only prevent working together on the current study but also on future studies. In addition, the clinical research industry is relatively small, so a reputation for unreasonable demands can negatively impact a sponsor's or site's ability to enter into relationships with the most sophisticated and desirable partners. The best approach is for the parties to discuss their concerns, explain their positions, and reach a mutually satisfactory agreement. Of course, this approach requires contract negotiators who understand the implications of the contract language and can articulate the rationale supporting their positions.

Because of the high stakes often involved, the indemnification clause is one of the most negotiated sections of a CTA and often one of the most contentious. While a well-drafted clause can mitigate some risks for *both* parties, most of the risks must be assigned to one party or the other. Both parties want to work together, so there is usually a middle ground where the parties can meet.

 

**Disclaimer**

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**Authors**


Michael Powers is a Senior Attorney with Buchanan Ingersoll & Rooney, PC. Contact him at 1.609.987.6804 or michael.powers@bipc.com

Kelly Smith is Managing Partner of the Virtus Group, a provider of contract management consulting and outsourcing solutions for small to mid-size pharma companies. Contact him at 1.415.425.7681 or kellylouissmith@gmail.com.


 