JOURNAL OF CLINICAL RESEARCH BEST PRACTICES

Vol. 16, No. 6, June 2020 "Happy Trials to You"

11 Questions About Confidential Disclosure Agreements in Clinical Research

By Kelly L. Smith

Before a research site can start conducting a clinical trial for a study sponsor, it must sign a contract, typically called a clinical trial agreement (CTA), which sets forth the rights and obligations of the parties. Before a research site can decide whether it wants to conduct the study and invest the time in negotiating a CTA, it usually needs certain information from the study sponsor. The study sponsor often considers some of this information to be very valuable trade secrets, so it does not want the site to disclose it to third parties like competitors or news outlets. To move forward, the study sponsor and research site therefore negotiate and sign a confidential disclosure agreement (CDA) to protect the sponsor's secret (proprietary) information and maybe that of the research site as well. CDAs can be used for other purposes related to clinical research, but this article will focus on this purpose.

Confidentiality agreements may also be referred to as non-disclosure agreements, secrecy agreements, or proprietary information agreements. Whatever the document is called, the disclosing party needs a solid agreement, not only for the transaction at hand but because a lack of care in protecting a trade secret might void *all* disclosure protections.

1, What's in a CDA?

A proper CDA will describe who the parties are, what confidential information will be exchanged, information not covered by the CDA, what happens if a party discloses or otherwise fails to keep confidential information secret, how long the CDA will stay in place, and related matters agreed by the parties.

2. What is a "disclosure"?

A disclosure occurs when the protected party in a CDA provides its confidential information to the other party. Although a CDA offers the disclosing party legal protection, not disclosing the information at all obviously affords even more protection. Similarly, the other party might prefer not to receive a disclosure, so it does not have to worry about protecting the information. Accordingly, one or both parties may prefer that a disclosure not occur.

3. What is "confidential information"?

A study sponsor's confidential information typically includes the contents of the protocol and investigators brochure, patient recruitment plans, other elements of the study plan, and any other information that, if disclosed, might potentially damage the sponsor or interfere in any way with its plans. Study sponsors generally follow a better-safe-than-sorry policy with respect to designating their information as proprietary.

4. What is a "trade secret"?

The term "trade secret" is often used to describe confidential information that gives someone an advantage in conducting its trade or business. Trade secrets are often referred to as the "secret sauce" or the "crown jewels" of a business. In some cases, a company may decline to file a patent application on a patentable invention because it would rather keep

the information secret and take the chance that a competitor will create the same invention. As a bonus, while patents have a limited life — 20 years in the U.S.— trade secrets can last forever.

5. What information is not protected by a CDA?

The disclosing party cannot expect the recipient of the disclosure to protect information that is not actually confidential, for example, information already public or later disclosed by the owner to the public, information already known by the recipient (with the right to disclose), or information that was independently developed by the recipient.

6. Are there circumstances in which the recipient can rightfully disclose confidential information?

The recipient can rightfully disclose information in a number of circumstances, for example, when ordered by a government authority or court of law or when to do so would protect the health of a study participant or the public.

7. What steps should the receiving party take to protect confidential information it has received?

The receiving party should have written policies and procedures to ensure that it does not violate the terms of a CDA. Common elements of such policies include controlling third-party confidential documents, disclosing third-party confidential information internally only on a need-to-know basis, and training personnel in how to recognize and protect third-party confidential information.

8. What are "marking requirements"?

It would simplify things for the recipient if the disclosing party disclosed its confidential information only in writing and always clearly marked with the words: "CONFIDENTIAL — DO NOT DISCLOSE."

However, it is impractical and unrealistic to expect the discloser to follow such rules 100% of the time. CDAs, therefore, usually include a provision that the recipient should protect *any* information it receives as confidential if a knowledgeable person in the industry would reasonably consider it so.

9. What happens if the receiving party violates the CDA?

In the event of a breach of the CDA, the disclosing party can seek one or more of three main types of remedies against the receiving party, depending on the circumstances:

- **Specific Performance or Actions.** The CDA might include a provision that requires the recipient to take a specific corrective action.
- **Money Damages.** The disclosing party can seek monetary compensation for damages in a court of law. Such compensation can very substantial for important trade secrets.
- **Injunctive Relief.** The disclosing party can ask a court of law to order the recipient do something (e.g., destroy a document) or not do something, (e.g., make further disclosures to limit potential damage from a disclosure).

10. How long does the obligation to protect confidential information last?

In theory, the obligation to protect confidential information should last as long as the secrecy of that information is valuable to the discloser. In practice, the term of confidentiality for a CDA typically ranges from three to seven years. It is unreasonable to bind someone to an obligation of confidentiality that lasts forever unless there is a valid reason. Indefinite duration would mean the recipient would have to retain a copy of the CDA and any related confidential documents or other "writings" in perpetuity in case the discloser were to come back decades later — after the actual people involved are long gone — complaining of injury. Even if the duration stated in the CDA has not expired, if the CDA is superseded by a CTA, the confidentiality provisions of the CTA typically supersede those of the CDA thereafter.

11. Whose law should govern if there is a dispute?

Both parties typically prefer that the laws of their own state or country will apply in any legal dispute. Given the relative interests of the parties when a CDA is typically signed, the laws of the study sponsor's state usually govern; but CDAs can also be silent on choice of law, especially if the research site is a state entity with sovereign immunity.

Conclusion

The above discussion is not meant to be comprehensive or entirely applicable to every circumstance. However, it does answer the most common questions about CDAs and should make it clear that CDAs should be read, understood and questioned before signing. MAGI's CDA template can be found at www.magiworld.org/Standards.

Author

Kelly L. Smith is President of Virtus Group, LLC. Contact him at 1.415.425.7681 or kelly@virtus-team.com.

