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Oft-Negotiated CDA Terms

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Both study sponsors and sites possess information that should be protected from unauthorized disclosure. In the course of conducting clinical research, some of this information must be exchanged by the parties involved in the research. Investigator's brochures, protocols and other scientific data may be disclosed, and the disclosing party does not want this information to find its way into the hands of a competitor. Confidentiality agreements, non-disclosure agreements, confidential disclosure agreements, etc., are all different names for a type of agreement with the same purpose — protecting this confidential information. Commonly referred to as a "CDA" in the clinical research industry, the study sponsor typically requires a research site to sign a CDA prior to receiving the protocol and other confidential information about the study. Other relationships, such as in an investigator-initiated study, may require both sides to disclose confidential information, in which case a "mutual" or "bilateral" CDA is required.

Some sites may sign CDAs after little or no review, but sites that are concerned about their obligations and liabilities under CDAs generally take more time to review these agreements. Given the current practice of providing CDA templates that favor the disclosing party, negotiations of one-sided CDAs often cause lengthy delays initiating clinical trial sites. This article discusses some of the commonly negotiated terms so both sides can understand why they are important.

Defining Confidential Information

"Provided to the Receiving Party"

The single most important element of a CDA is the definition of confidential information. This definition should identify exactly what information requires protection so the receiving party can identify and fulfill its obligations with certainty. Here is an example of a poorly written definition of confidential information:

> "Confidential Information" means all information of the Disclosing Party, including, without limitation, technical and business data, intellectual property, research and development strategies, research results, protocols and investigator brochures.

According to this definition, the receiving party would have to treat *all* information of the disclosing party as confidential, even if the receiving party *did not receive* the information from the disclosing party *pursuant to the CDA*. A researcher working on a different program who knows nothing about this study might receive information from the disclosing party and be bound by a CDA that he or she does not even know exists. Therefore, an improved definition requires the information to be *provided by the disclosing party to the receiving party*. This might seem like an obvious qualification, but it is commonly absent, as in the example above. Here is an example of a quick fix to correct this problem:

> "Confidential *Information" means all information ~~of~~ provided by the Disclosing Party to the Receiving Party, including*, without limitation, technical and business data, intellectual property, research and development strategies, research results, protocols and investigator brochures.

Even with this improvement, however, this definition is still defective.

"In Connection with the Study"

The sponsor and site may have multiple CDAs in place for various studies or other matters. Unless the definition of confidential information is tied to a particular study, it would be impossible for a site or sponsor to determine which agreement applies to a specific piece of confidential information. The CDA should, therefore, specifically define confidential information as relating to a particular study. Taking the language from above, here is a simple fix to address these problems:

> "Confidential Information" means all information provided by the Disclosing Party to the Receiving Party *in connection with the Study,* including, without limitation, technical and business data, intellectual property, research and development strategies, research results, protocols and investigator brochures.

"Of a Confidential and/or Proprietary Nature"

The above language does not address the fact that not all information provided by the disclosing party is confidential. For example, the informed consent form (and possibly risk information from the investigator's brochure) will need to be provided to patients without any obligation of confidentiality. These disclosures would not be allowed if the definition were to remain as previously written.

To solve this problem, the following compromise language is generally accepted throughout the research industry:

> "Confidential Information" means all information *of a confidential and proprietary nature* provided by the Disclosing Party to the Receiving Party in connection with the Study, including, without limitation, technical and business data, intellectual property, research and development strategies, research results, protocols and investigator brochures.
>
> or
>
> "Confidential Information" means all information provided by the Disclosing Party to the Receiving Party in connection with the Study, *which, if not marked or otherwise identified as confidential at or about the time of disclosure, a reasonable person familiar with the clinical research industry would deem to be confidential given the nature of the information or the circumstances surrounding its disclosure*, including, without limitation, technical and business data, intellectual property, research and development strategies, research results, protocols and investigator brochures.

The "Laundry List"

Most definitions of confidential information include a "laundry list" of specific categories of confidential information. Often, the laundry-list categories are vague and do not clearly identify specific instances of confidential information, leaving the site uncertain as to what information it must protect. For example, some technical data may not be confidential. Unless the list is narrowly tailored to identify disclosures with sufficient specificity, it is preferable to use permissive language before listing various types of confidential information, as indicated in the example below:

> "Confidential Information" means all information of a confidential and proprietary nature provided by the Disclosing Party to the Receiving Party in connection with the Study, *and may include*, without limitation, technical and business data, intellectual property, research and development strategies, research results, protocols and investigator brochures.

Exceptions to Confidentiality

All CDAs should include the following six exceptions to confidential information, which can be combined and described in various degrees of detail:

- *Information that is publicly available prior to disclosure.* "Public domain" is not the same as "publicly available." The term "public domain" is a legal term of art that is defined in Black's Law Dictionary as "*The universe of inventions and creative works that are not protected by intellectual-property rights…*" For example, even though a movie is available to the public, it is not in the public domain, as it is owned by the copyright holder.
- *Information that becomes publicly available after disclosure.*
- *Information that is known to the receiving party prior to disclosure.* If the disclosing party wants to include an exception to this exception, such as "and was not acquired from the disclosing party," it should be limited to information protected under a prior confidentiality agreement to avoid any conflict of terms.
- *Information that is subsequently disclosed to the receiving party by a third party.*
- *Information that is independently developed by the receiving party.*
- *Information that is required to be disclosed by law.* If the disclosing party wants to be notified prior to a legally required disclosure, the CDA should address scenarios in which prior notification is not legally permitted. For example, investigations conducted by the SEC might require secrecy and the receiving party might not be permitted to provide prior notice. Some "required disclosure" terms compel the receiving party to contest the disclosure on the disclosing party's behalf. The receiving party should consider whether it is willing to incur the legal costs in protecting the disclosing party's confidential information from any required disclosure or if it is preferable to allow the disclosing party to contest the requirement.

Who Can Use the Confidential Information and How?

CDAs should clearly identify *who* can use the confidential information and *how* it can be used. The receiving party should always have the right to use confidential information for the intended purpose of a CDA, for example, "for review and consideration of the study."

Some CDAs state that confidential information may not be disclosed to anyone at all, but this restriction is impossible in clinical research. The protocol and other confidential information must be disclosed to investigators, sub-investigators, sub-sites, the IRB, management, administrators and others who will be involved in the research. The CDA must address these "downstream" disclosures.

Often, a CDA allows downstream disclosures, but only after the receiving party's personnel "have been advised of the confidential nature of the disclosing party's confidential information and are bound to the terms of this agreement." This requirement means that the primary recipient needs to identify every possible downstream recipient in advance and obtain his or her signature on the CDA, which is impractical in most organizations of any size. The following language provides a more practical solution:

> The receiving party may disclose the disclosing party's confidential information to its employees, affiliates and agents who have a need to know the information and who are bound by obligations of confidentiality substantially similar to those contained herein.

Effective Date and Term

CDAs should state a time limit for obligations of confidentiality to avoid imposing burdensome perpetual duties on the receiving party that would extend beyond a realistic period of confidentiality.

The time limit should be definite and easily determinable. Some CDAs contain vague time limits, such as, "five years from the date of last disclosure." This clause is problematic when there is an unlimited period for disclosure, which could allow obligations of confidentiality to continue indefinitely. Generally, a range of three to five years from the effective date of the CDA is standard in clinical research.

Other Terms

CDAs sometimes include the following issues, so sites should determine their policies and practices for addressing them.

Retention of Confidential Information

Some CDAs require the receiving party to return the disclosing party's confidential information upon termination of the agreement or completion of the project. The receiving party should consider whether this request is practical. For many sites, it would be an immense burden to track the retention requirements under numerous agreements, each with different termination dates. Therefore, from a site's perspective, it is generally preferable to have the disclosing party request the return of specific confidential information. Even so, it might not be possible for the site to retrieve every copy unless it has a very robust document management system. The receiving party should also consider whether it has procedures in place to return or destroy "electronic" or "intangible" confidential information, if requested.

If the disclosing party requires the receiving party to return or destroy its confidential information, the receiving party should always have the right to retain one copy of the confidential information to determine its continuing obligations under the agreement. Without retaining a copy, it would be impossible for the receiving party to prove what information it received pursuant to the CDA, and it would be unable to defend itself in a possible CDA-related dispute.

Marking Requirement

It is much easier for the receiving party to identify and protect confidential information when the disclosing party has marked it as confidential. The disclosing party is in the best position to identify what information it considers confidential, and marking information removes any ambiguity. With a marking requirement, confidential information that is disclosed orally should be reduced to writing and provided to the receiving party in a written format to avoid any uncertainty. However, because marking information can be burdensome and error-prone, a disclosing party may be unwilling to accept a marking requirement.

Marking documents as confidential is especially useful for downstream disclosures, since those recipients might not understand their significance in the absence of a marking. If the disclosing party wants to notify everyone who receives the information that it is confidential, the disclosing party should bear the responsibility of marking its information as such.

Intellectual Property Transfer

If the disclosing party is concerned about an inadvertent transfer of intellectual property, it could include a statement to the effect that disclosure does not constitute a transfer of any rights to the intellectual property other than for the limited purpose of the CDA.

Licenses

A CDA might state that the recipient of confidential information does not receive any "license" or "right" to the confidential information, but, technically, this is not true. By its nature, a CDA gives the recipient of confidential information a "license" or "right" to use confidential information, albeit very limited.

Injunctive Relief

CDAs often contain terms allowing the disclosing party to obtain injunctive relief to address any breach of the agreement. Injunctive relief means that the disclosing party can obtain a court order requiring the receiving party to take or not take certain actions. However, not every actual or potential breach of a CDA results in irreparable harm or is suitable for injunctive relief. The receiving party should determine whether such provisions can be accepted in general or on a case by case basis.

Attorney's Fees and Bond Posting

Any terms that predetermine the provisions of attorney's fees or waive a bond-posting requirement should be considered carefully, especially if they are one-sided. (Courts generally require a financial bond from the party seeking an injunction to guard against frivolous lawsuits.)

Conclusion

Different studies involve different types of confidential information of different value, so CDAs should be drafted and negotiated accordingly.

With or without CDAs, research sites should follow reasonable practices for protecting confidential information provided by other parties; they probably already do so for private health information. Although CDAs are rarely litigated, they serve an important purpose: protecting the confidentiality of valuable proprietary information.

The reality is that certain information must be kept confidential when conducting clinical research. It may be hard to identify this information at the onset of a research relationship, but most people know confidential information when they see it. CDA templates that grant favorable terms to the disclosing party while imposing burdensome requirements on the receiving party create an impediment to rapidly starting a study. By starting with reasonable confidentiality terms, both sides can achieve their objectives without countless hours of negotiation.

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