

Confidential Disclosure Agreements: What's the Big Deal?

What's so special about CDAs?

- ∞ A company may want to send information it considers proprietary or confidential to the PI so that he/she can decide whether to participate in a clinical trial. The company wishes to safeguard its proprietary or confidential information. The mechanism to protect the disclosure is the execution of a Confidential Disclosure Agreement (CDA).
- ∞ In order to protect the University and the PI, all incoming CDA's requiring University signature need to be reviewed, negotiated and executed by OSR.
- ∞ Negotiation of CDAs can be minimal; however, most CDAs include language that OSR cannot accept without revisions. For example, the University will not agree to subject itself to the laws of other states.

Background

ACADEMIC INSTITUTION

- ⌘ Academic institutions are protective of their academic freedom to share their knowledge with their peers
- ⌘ Academic institutions are protective of their right to publish

SPONSOR

- ⌘ Sponsors are very protective of their IP as it is an important asset in the competitive field of pharmaceutical development and sales

Background (cont.)

ACADEMIC INSTITUTION

- ☞ Facilitate investigator's access to Sponsor's information in order to evaluate and determine if he/she wishes to participate in the study
- ☞ Limit the scope of what is considered confidential
- ☞ Limit the scope of what could be considered breach and limit potential liability

SPONSOR

- ☞ Protect Sponsor's non-public, confidential, proprietary information when disclosed for a possible study at clinical trial site
- ☞ Provide legal remedy in the event of breach

Background (cont.)

The CDA should:

- ∞ Specify how information can be used

- ∞ Specify to which individuals and entities PI can disclose information to:
 - Medical affiliates
 - Employees, study staff
 - Agents, IRB members

- ∞ Limit how long the information has to be kept confidential

Agreement and Purpose

- ∞ Identify the parties to the Agreement

- ∞ Define Discloser & Recipient
 - Unilateral or Bilateral

- ∞ The “Purpose” establishes the terms under which information will be disclosed
 - Information to be disclosed is “confidential” to discloser
 - The parties will review the disclosure in order to determine if academic institution will participate as a possible research site for one or more Sponsor clinical studies

Confidential Information

- ∞ Disclosed in any format -- written, electronic, oral or otherwise
- ∞ Includes - “patent application, ~~trade secret~~ or other proprietary information of a technical, business or other nature provided in connection with the Purpose”
- ∞ May also include
 - The existence and terms of the CDA
 - Study title
- ∞ Excludes
 - Data generated in the conduct of a Study
 - Information disclosed before execution of the CDA

Confidential Information (cont.)

Other Exclusions:

- ∞ Information that is known or becomes known to the public through no breach of this Agreement by Recipient;
- ∞ Information lawfully in Recipient's possession prior to disclosure by or on behalf of Discloser, as shown by written records or comparable evidence;
- ∞ Information obtained by Recipient from a third party who, to Recipient's knowledge, has the right to disclose the information; or
- ∞ Information developed independently, without reliance on the Discloser's Confidential Information, by Recipient, as evidenced by written documentation contemporaneous with the development.

Marking Information as “Confidential”

- ∞ It is the Discloser’s responsibility to identify such document as confidential at time of disclosure.
- ∞ “Discloser will make reasonable efforts to mark or otherwise identify its Confidential Information as confidential”
 - If orally disclosed, follow-up within 30 days in writing to confirm that it is confidential
 - Provided that any information that a reasonable person knowledgeable about clinical research would judge confidential will still be treated as Confidential Information even if it is not marked as “confidential”

Obligations of Use and Disclosure

- ✎ Recipient may only use Confidential Information for the Purpose
 - Not for commercialization purposes, e.g., reverse engineering or product development

- ✎ Recipient may disclose Confidential Information only to (a) its employees, staff, consultants, agents, IRB members, ethics committees, and other persons and entities (medical affiliates) in order to accomplish the Purpose (on a need-to-know basis), who are bound by a similar obligation of confidentiality and non-use (“Bound Parties”), and (b) regulatory authorities

- ✎ Recipient shall protect Confidential Information with at the least same care used by Recipient for its own confidential information, and in no event use less than reasonable care

Obligations of Use and Disclosure (cont.)

- ⌘ Recipient must promptly notify and cooperate with Discloser if it discovers any loss or compromise of Confidential Information
- ⌘ Recipient will be responsible for its failure and the failure of its Bound Parties to comply with the terms of the Agreement

Compelled Disclosure

- ⌘ Recipient may disclose Confidential Information to the extent required by law, regulation, authorized governmental body, court or judicial order, provided, however, that Recipient promptly provides to Discloser prior written notice of such disclosure and cooperates with Discloser, at Discloser's expense, in its efforts in obtaining an order or other remedy protecting the Confidential Information from public disclosure.
- ⌘ This is not an exception to the definition of confidential information. Information disclosed shall still otherwise remain subject to the obligations of confidentiality and non-use.

Termination & Survival

- ∞ “Effective Date” – the term commences on last date of signature
- ∞ “Effective Period” – the effective period of the Agreement under which disclosures can to be made
 - 1 to 2 years from Effective Date
- ∞ The obligations for confidentiality and non-use expire at a stated term
 - 3, 5 or 7 year term from Effective Date / Disclosure Date / Termination Date
- ∞ Survival of other terms “that by their nature should survive”
- ∞ Promptly after Discloser’s written request, Recipient shall return or destroy the Confidential Information
 - May keep at least one copy in secure location

Remedy for Breach

∞ “A breach of this Agreement may cause irreparable damage to Discloser that may not be addressed adequately by money damages. In case of breach or default of this Agreement, Discloser may pursue all contractual and other remedies, both legal and equitable for actual [and consequential] damages. In addition to any other remedies that may be available, Discloser is entitled to seek injunctive relief to prevent or restrain a breach”

- Defines the scope of damage and remedies
- Discloser may seek injunction as a remedy to prevent further breach of confidentiality

Governing Law & Venue

- ∞ Choice of governing law and location of courts
 - At issue for non-profit academic institutions is familiarity with state law and costs of mounting a defense
 - For bilateral CDAs – the home state of the defendant party against whom the claim is brought
 - For both unilateral and bilateral CDAs, the parties may choose to delete this section and remain silent on jurisdiction and governing law

General Provisions

- ☞ Discloser is the owner of Confidential Information. Discloser grants NO rights to Recipient except the limited right to use the Confidential Information strictly for the Purpose
- ☞ Agreement supersedes prior agreements
- ☞ Modifications must be in writing
- ☞ Severance – invalid provisions will not affect entire agreement
- ☞ Not assignable, except by mutual consent
- ☞ Execution in counterparts, [facsimile or e-mail] is acceptable

Miscellaneous

- ∞ Export Control Language
- ∞ Master CDAs

THANK YOU!

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