



**Boston University
Office of Sponsored Programs**

Negotiation of Confidential Disclosure Agreements: Standard Operating Procedures

I. Background and Purpose

Prior to making a determination that they desire to move forward with a research project, Boston University (the "Institution") and the proposed provider of research support (the "Sponsor") often engage in discussions that involve one or both of the parties disclosing information that it considers confidential or proprietary to the other party. Before such a discussion occurs, it is important to implement a Confidential Disclosure Agreement ("CDA") so that the parties may communicate freely and openly without concern that their confidential information will be put at risk. This document may also be referred to as a "Confidentiality Agreement," "Non-Disclosure Agreement" or "NDA".

In the case of a CDA entered into in anticipation of a clinical trial, the agreement typically covers only confidential disclosures from the Sponsor to the relevant Investigator (a "One-Way In" or "Incoming" CDA). It is the Institution's preference that such CDAs be executed by the Investigator as an individual, as opposed to the Institution. However, this is not always acceptable to the Sponsor, and if necessary, the CDA will be signed by an authorized representative of the Institution in order to move the evaluation process forward.

In the case of a CDA entered into in anticipation of a sponsored research project, it is highly likely that the Investigator will be disclosing the Institution's confidential information, as it will be important for the Sponsor to have a sufficiently deep understanding of the Investigator's research to make a determination as to whether it wants to fund such work. The Sponsor may or may not also disclose confidential information. If it does, the CDA will be "Mutual," or "Two-Way," and if it does not, the CDA will be "One-Way Out" or "Outgoing."

In addition to imposing a duty of confidentiality on the party receiving confidential information, a CDA will typically provide that any confidential information disclosed may be used only for a stated purpose, which may be as general as "a proposed business relationship between the parties," or may be described in more detail.

The goal of the Contracts & Agreements group within the Office of Sponsored Programs ("C&A") is to quickly finalize and execute each CDA that is presented for review so that the parties may

commence confidential discussions as quickly as possible. CDAs do not tend to vary extensively, and so it is often easy for the two sides to come to a resolution. The focus of C&A is to limit the obligations it accepts in the CDA (for instance, keeping the duration of the obligation to maintain the secrecy of incoming confidential information as short as possible), while ensuring that any outgoing confidential information is adequately protected. Academic institutions are less accustomed to keeping information secret than are commercial entities, due to the fact that sharing of information is central to their mission, and so it is important that C&A not compel either the Institution or the Investigator to take on obligations that it/he/she will have difficulty meeting.

II. Process

The process of submitting, negotiating and finalizing a CDA is simple. When an Investigator receives a CDA from a Sponsor, he/she should forward it to Associate Director, Contracts & Agreements, in OSP. The Associate Director or a member of his/her team will review the CDA, provide any necessary comments to the Sponsor and coordinate the signature process. When an Investigator is contemplating disclosing Institution confidential information to a third party for any reason, he/she should contact the Associate Director and together they will determine the scope of the agreement and any special terms that should be included, and C&A will provide a draft to the Sponsor for review and then handle the remaining negotiations and execution process.

III. Negotiation of Terms

Some of the key provisions in a CDA are the following:

- Definition of “Confidential Information”: Should not include trade secrets. The Institution prefers to receive as little confidential information from a third party as possible, and will not hold trade secrets confidential any longer than any other type of information provided.
 - Exclusions: The obligations of confidentiality should not apply to information that: (a) was in the Receiving Party’s possession prior to receipt under the CDA; (b) was or becomes publicly known; is received from a third party free of confidentiality obligations; or is independently developed by the Receiving Party without reference to or reliance upon any confidential information received under the CDA. The Receiving Party must also be entitled to disclose information as required by law or court order, without such disclosure constituting a breach of the CDA. These terms are relatively standard among all CDAs.

- Marking requirement: The Institution prefers that all incoming information be clearly marked as confidential, and that information provided orally or visually be identified as confidential at the time of disclosure and summarized in a writing by the Disclosing Party within 30 days. This way, it is abundantly clear what information must be maintained in secrecy. For outgoing CDAs, however, the preference is not to include a marking requirement.
- Duration of Obligations: 3 years best; 5 years acceptable; 7 years outside limit (Note: For CDAs executed in anticipation of a clinical trial, the period may be extended to 10 years.)
- Standard of Care: For incoming CDAs, the Institution or the Investigator will agree to use “reasonable efforts, but no less than the efforts used to protect its/his/her own confidential information of a similar nature” to maintain the confidentiality of information received under the CDA.
- Internal Dissemination of Information: For incoming CDAs, the CDA should provide that confidential information may be shared with employees and personnel who have a “need to know” the information and who are “informed” or “made aware” of the obligations of confidentiality set forth in the agreement, and the Institution will agree to be responsible for compliance by such individuals with the terms of the CDA. Because such persons do not sign a copy of the CDA or any other document obligating them to the terms of any specific CDA, language stating that they have “agreed to be bound by the terms of the CDA” should be avoided. For outgoing MTAs, this language should be included if possible.
- No Licenses: The CDA should make clear that the sharing of confidential information thereunder does not constitute a license to any patent or other intellectual property rights of the Disclosing Party.
- No Warranties: For outgoing CDAs, it is important to state that the Institution or the Investigator makes no warranties with respect to the confidential information provided to the Receiving Party under the CDA and shall not be liable for *any* damages as a result of the Receiving Party’s use of the information.
- No Obligations: The CDA should be clear that it does not impose any obligation on either party to enter into any agreement or relationship with the other party in the future
- Remedies for Breach: Often, the party disclosing information under the CDA will want to include a provision making it clear that recovery of money damages will not be the sole remedy for a breach by the other party of the terms of the agreement, because in such event, the most effective remedy will be obtaining an injunction against the breaching party preventing them from continuing the breach. However, the CDA should state

simply that a breach of the agreement “*may* [not “*will*”] cause irreparable damage” and that the non-breaching party will be “entitled to *seek* injunctive relief” [not “entitled to injunctive relief”].

- Governing Law: As with other agreements executed by the Institution or an Investigator, it is preferable to designate Massachusetts law as the governing law, and to provide for resolution of disputes within Massachusetts (jurisdiction). It is also acceptable to remain silent.