

Confidential Disclosure Agreement (“CDA”) FAQs

1. What is a Confidential Disclosure Agreement (CDA)?

A Confidential Disclosure Agreement (“CDA”), sometimes called a “Confidentiality Agreement” or “Non-Disclosure Agreement,” is a legal document which ensures the confidentiality or “secrecy” of information that one party discloses to another party. A signed CDA may be required before an industry sponsor agrees to disclose its proprietary information (e.g., the study protocol) to an investigator. The Office of Clinical Trials (OCT) is responsible for reviewing CDAs related to the evaluation of industry-supported clinical research studies conducted at the Medical Center.

2. Who are the Parties to a CDA?

The Medical Center prefers that CDAs be entered into directly between a sponsor and the individual faculty member evaluating the clinical research study. In such cases, the parties to the CDA will be the sponsor and the faculty member. However, some companies require that an institution sign the CDA. In those instances, the parties to the CDA will be the sponsor and the institution, namely “New York University School of Medicine, an administrative unit of New York University.”

3. What are my obligations under a CDA?

While most CDAs contain similar obligations, there may be additional obligations or somewhat different obligations under your specific CDA than the obligations noted below. You are responsible for reviewing and complying with the terms and conditions set forth in your specific CDA, whether you sign it or the Medical Center enters into it on your behalf.

Under virtually any CDA, you are responsible for maintaining the confidentiality of the information which is defined as confidential under the CDA, for not disclosing such information except as permitted under the CDA, and for not using such information except for the evaluation of the proposed clinical trial. As part of this obligation, you should take care to treat the information like your own confidential information or even your patients’ private information. You should tell anyone at the Medical Center with whom you share the confidential information provided to you of the confidential nature of the information and your obligations under the CDA. You should refrain from co-mingling the confidential information with other information. You should return or destroy the information if required by the disclosing party and keep one copy for your records if permitted by the CDA. If the evaluation results in your and the Medical Center’s agreement to perform the clinical trial, you should review and follow any confidentiality obligations outlined in the resulting clinical trial agreement.

4. I have been presented with a CDA with the sponsor and NYU School of Medicine as the parties. I need to have this CDA signed ASAP. What should I do?

DON’T SIGN THIS DOCUMENT. You are not authorized to sign CDAs for the institution. Only delegated signatories in the OCT are authorized to sign CDAs with industry sponsors related to clinical research studies.

Instead, email the CDA to the OCT Contracts Manager (Susan.Shin.Andersen@nyumc.org) or the Clinical Research Management Coordinator (“CRMC”) for your department. The OCT will help you obtain a Study Number (“S #”) for the CDA and then will negotiate the CDA terms with the sponsor. The OCT makes every effort to review initial drafts of CDAs within one to two business days after receiving the CDA. On average, the process of review, negotiation and execution of a CDA takes between 10 to 15 business days.

5. I have been presented with a CDA with only the sponsor's and my name on it. As a faculty member of NYU School of Medicine, may I sign the document without review and negotiation by the OCT?

Please see the one-page [Confidential Disclosure Agreement Checklist for Sponsor-Faculty/PI CDAs](#) covering Clinical Trial Evaluations available for guidance on whether you may sign the document without an OCT review and negotiation.

While you may not need to under this Checklist, you are encouraged to submit every CDA to the OCT for advice and guidance. The OCT will review the CDA in accordance with NYU Medical Center's practices and guidelines, and advise you of those changes that are "required" by the Medical Center and those that are "recommendations" to you. The recommendations are advisory only and you are free to negotiate the CDA with the sponsor, provided that you send a copy of the fully signed CDA to the OCT. If you prefer, the OCT can negotiate the CDA on your behalf.

If you want to give the OCT the opportunity to review, please send it by e-mail to the OCT Contracts Manager (Susan.Shin.Andersen@nyumc.org).

6. What are the important contracting issues in CDAs? When I review CDAs naming me as a party, what should I watch for? When the OCT does the review, what does the OCT look for and negotiate?

Whether or not you review the CDA on your own, you should be aware of the following Medical Center practices and standards when reviewing and negotiating CDAs.

- a) Identification of the Receiving Party: Under Medical Center policies, if the party receiving disclosures is NYU School of Medicine or any other unit or division of New York University or the Medical Center, the CDA requires review and approval by the OCT. If the receiving party is you personally, you may negotiate the CDA personally. See Question #5 above.
- b) NYU Obligations require OCT Review: A CDA that does not have NYU as a party should not impose obligations on NYU. If obligations are imposed on NYU, you need to send these to the OCT Contracts Manager (Susan.Shin.Andersen@nyumc.org).
- c) Avoid an Overly Broad Definition of Confidential Information: A CDA should cover only disclosures to you regarding the specific matter (e.g., trial protocol or investigational drug or device) you are seeking to evaluate. It should be labeled or marked as "confidential." It should not cover all kinds of business and other information provided by the industry sponsor to you or to others at NYU. It should not cover information, data or results generated by you or NYU. The CDA's confidentiality obligations should not cover information that is already public, later becomes public, is received from a third party without obligations of confidentiality, or is independently developed.
- d) Define the Contract Term: CDAs should stipulate that disclosures of confidential information may only be made over a period of a few months or, at most, a couple of years. If there is no specified disclosure period or "term," the CDA could last forever and cover disclosures beyond those you can reasonably anticipate now. A CDA should have an expiration date and a way for you to "terminate without cause."

- e) Avoid “Evergreen” Survival Terms: CDAs should not impose obligations of confidentiality indefinitely. In other words, after a certain length of time, the recipient of confidential information should not be required to keep the information confidential. As a general matter, NYU will not agree to a confidentiality survival period longer than 5 to 7 years from date of disclosure of the confidential information.
- f) Avoid “Best Efforts”: NYU will not agree to use greater efforts of confidentiality than what NYU does for its own information. For example, NYU will only agree to use “reasonable efforts” on matters related to confidential information and will not agree to use “best efforts” in a CDA.
- g) Include Permissible Disclosures. You and NYU should also have the right to disclose the sponsor’s information when legally required (e.g., pursuant to a subpoena) and to disclose confidential information as needed to other employees within NYU.
- h) Avoid Having to Return/Destroy Everything: Most CDAs require the return or destruction of the Confidential Information upon termination of the CDA. Complying with this requirement could compromise a legal defense should something go wrong. NYU insists on the right to retain one copy of the Confidential Information for internal legal records and the right to maintain copies on its backed-up electronic systems.
- i) Avoid Invention Assignments: The assignment of new inventions or other intellectual property in CDA is NOT acceptable. These provisions could conflict with your obligations to NYU under its patent and other policies. They are not standard for CDAs and do not belong in CDAs. ALWAYS send CDAs with these terms to the OCT’s Contracts Manager (Susan.Shin.Andersen@nyumc.org).
- j) Avoid Indemnification: NYU does not agree to indemnification terms in CDAs. Agreeing to a CDA that includes an indemnification or other liability clause may put NYU or you at substantial financial risk. In our experience, no CDA ever needs to have an indemnification clause.
- k) Avoid Mandatory Relief: NYU does not agree to provisions that entitle the sponsor to injunctive relief or specific performance upon a contract breach. This means that the sponsor could obtain a court order restricting your or NYU’s activities based on its allegation of a contract breach without proving it. For instance, this term could help a sponsor temporarily block a scientific publication if the sponsor alleges that the paper includes its confidential information. NYU will agree that a disclosing party may seek injunctive relief, but will not agree that the sponsor is entitled to it.
- l) Avoid Non-NY Governing Law/Jurisdiction: NYU does NOT agree to arbitration, non-NY governing law, or non-NY jurisdiction terms in CDAs. These provisions could result in having to defend a claim in another country or state under an unfamiliar law.

Please remember that if you encounter any unfavorable terms in a CDA you are negotiating on your own behalf, the OCT is available for consultation on how best to address these terms. Contact the OCT’s Contracts Manager by e-mail at Susan.Shin.Andersen@nyumc.org.

7. If I need a CDA with a company before sharing information developed at NYU, where can I find a suitable template?

Please contact the OCT’s Contracts Manager by e-mail at Susan.Shin.Andersen@nyumc.org.