

## Columbia University Medical Center

**Purpose:** This document describes Columbia University Medical Center 's standard operation procedures (SOP) for executing Confidentiality Disclosure Agreements with external research sponsors, including, but not limited to, pharmaceutical or device companies, other universities, and non-profit consortiums.

**Responsibility:** This SOP applies to those members of the clinical research team involved in the process of executing Confidentiality Disclosure Agreements. These include:

- Principal investigators
- Sub-investigators
- Fellows
- Study coordinators
- Clinical research nurse administrators
- Office managers
- Administrative assistants

### Process overview

- I. Initial contact with sponsor
- II. Execution
- III. Contact with Clinical Trials Office

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### I) Initial contact with sponsor

- A. Sponsor contacts site personnel to evaluate interest in its research study.
- B. Site personnel request a current sponsor CDA. Site personnel request that an electronic copy of the CDA be sent to the Manager of Contracts with the appropriate sponsor contact information.
- C. The Manager of Contracts assigns the CDA to a Project Officer who reviews and revises the CDA and then returns the revised draft to the sponsor contact for review and commentary.
- D. If no sponsor template exists, a Columbia University template is available through the Clinical Trials Office.
- E. If the sponsor's CDA is sent directly to the site, the document should be forwarded to the Manager of Contracts.
- F. No site personnel, including the Principal Investigator, should sign a CDA before its review by the Clinical Trials Office.

### II) Execution

The CDA is signed by the Director of the Clinical Trials Office and the sponsor.

For CDAs that require the Principal Investigator's signature, the CDA is sent to the Principal Investigator for signing after the terms have been agreed upon.

The Principal Investigator's office is notified when the CDA is fully executed and available for pick up from the Clinical Trials Office.

### III) Contact with Clinical Trials Office

E-mail CDA documents and related communications to the Clinical Trials Office at [ctocda@ColumbiaClinicalTrials.org](mailto:ctocda@ColumbiaClinicalTrials.org).