UConn Health
Office of Clinical & Translational Research
Standard Operating Procedures

Title: Confidential Disclosure Agreements/CDA (Industry Sponsored)	
Relates to Policy/Procedure:301-12 302-12	
SOP#: 300-12	Version 2.0
Prepared by: J. Kulko, MS, MSN	Original date: June 28, 2012
Approved by: J. Kulko, MS, MSN	Date approved: August 19, 2016

Purpose and Applicability: The purpose of this document is to establish a uniform process for the preparation, review, negotiation and approval of Industry initiated CDAs received by investigators at the UConn Health

Background and Significance: A Confidential Disclosure Agreement (also referred to as a "Confidentiality Agreement", "NDA" or "Nondisclosure Agreement") protects a party's proprietary or non-public information, and is typically used when parties must disclose such information in order to evaluate a possible relationship with the other party. Generally, if the UConn Health investigator expects to disclose any confidential information to the outside entity, then the Confidentiality Agreement should be set up between UConn Health and the other party.

No SOPs exist at UConn Health that describes the processes that govern the review and approval of CDAs. The CDA, which is sent to UConn Health investigators as the first step in establishing a possible relationship with the other party, may culminate in UConn Health's participation in an Industry sponsored clinical trial.

Scope: This policy governs all CDAs that are negotiated between UConn Health and an Industry Sponsor/ Contract Research Organization (CRO) wishing to engage a UConn Health investigator as a site PI of a clinical trial and open that clinical trial at UConn Health.

Responsibilities: The investigator is responsible for sending CDAs to the OCTR Contracts Specialist for review and negotiation if the Sponsor/CRO is seeking authorization on behalf of UConn Health.
The OCTR Contracts Specialist is responsible for the review and negotiation of industry sponsored CDAs that require UConn Health authorization.

A. Investigator emails CDA to Contracts Specialist in OCTR

B. The OCTR Contracts Specialist:
   a. Reviews CDA
   b. Redlines CDA
   c. Sends changes to Sponsor/CRO
   d. Reviews Sponsor's counter revisions (if any)
   e. Accepts final version
   f. Keeps computer file of fully executed CDA

C. The OCTR Fiscal Assistant in OCTR is responsible for:

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a. Entering new CDA in Access database
b. Obtaining signatures of investigator and Designated Institutional Signatory* via E-mail
c. Sending CDA to Sponsor/CRO for signature via E-mail
d. Contacting Sponsor/CRO regarding status of CDA
e. E-mailing the fully-executed CDA to the PI and/or study coordinator
f. Keeping a computer file of fully executed CDA on OCTR I drive

Procedural Steps:

These procedural steps are done by the appropriate OCTR staff and include:

a. New CDA is entered in Access database including date received
b. Contact person from Sponsor/CRO is identified
c. CDA is reviewed
d. CDA is redlined
e. Contract Specialist negotiates with Sponsor/CRO
f. Signatures of PI and Designated Institutional Signatory* are obtained via E-mail
g. Document sent via E-mail
h. Status of CDA is tracked
i. PI is notified of status
j. Receipt date officially executed CDA from Sponsor/CRO is recorded.
k. Electronic copy of fully executed CDA is maintained on OCTR I drive

Revision date: 8/19/16; 7/27/12	Revised by: J. Kulko
Reason for revision: 2.0 No longer require wet ink original of signature; process of obtaining signatures done via e-mail; name change 1.0 Documentation procedure for noting *"CDA not signed by UCHC institutional official"* if subsequent contract negotiations occur as a result of the CDA.	
Date revised version sent to archives & current revision version # advanced:8/19/16	

*See List of Institutional Signatories