UConn Health
Office of Clinical & Translational Research
Standard Operating Procedures

Title: Essential Components of CDA (Industry Sponsored)	
Relates to Policy: 300-12	
SOP#: 311-16	Version 1.0
Prepared by: J. Kulko, MS, MSN	Original date: August 19, 2016
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.

Clinical Research:
1) Patient-oriented research conducted with human subjects (or on material of human origin such as tissues, specimens, and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. It includes: (a) mechanisms of human disease, (b), therapeutic interventions, (c) clinical trials, or (d) development of new technologies.
2) Epidemiological and behavioral studies.
3) Outcomes research and health services research
Studies falling under 45 CFR 46.101(b) (4) (Exemption 4) are not considered clinical research by this definition. [1]

Clinical Trial: A research study[2] in which one or more human subjects[3] are prospectively assigned[4] to one or more interventions[5] (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.[6]
2,3,4,5,6

[1] NIH glossary
http://grants.nih.gov/grants/glossary.htm#C
NIH Revised definition
[2] See Common Rule definition of "research" at 45 CFR 46.102(d).
[3] See Common Rule definition of "human subject" at 45 CFR 46.102(f).

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And the Institution (UConn Health) who may be providing:

a. Subjects
b. Data and/or Results
c. Publication, Input into Publication
d. Input into further Intellectual Property

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

The CDA, at a minimum must include:

A. Sponsor Name
B. Name of PI and name of Institution
C. Governing law: Connecticut
D. Exceptions to Confidential Information:
   a. is already known to UConn Health through no fault of UConn Health,
   b. after disclosure, becomes a part of the public domain by disclosure through no violation of the CDA,
   c. has been lawfully in UConn Health's possession prior to any disclosure under this Agreement as evidenced by written records
   d. is lawfully disclosed by a third party to UConn Health where such third party did not acquire the Confidential Information under a still effective obligation of confidentiality to disclosing party
   e. is independently developed by UConn Health as evidenced by written records without the benefit of confidential information, and
   f. is required to be disclosed by law or court order.
E. Indemnification: UConn Health cannot indemnify the Sponsor
F. No Commitment to Study: By signing the CDA, the Principal Investigator has not agreed to conduct the study but has agreed to evaluate the confidential information and secure said information.
G. Definition of Confidential Information: There must be an adequate description/definition of the confidential information

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4 The term "prospectively assigned" refers to a pre-defined process (e.g., randomization) specified in an approved protocol that stipulates the assignment of research subjects (individually or in clusters) to one or more arms (e.g., intervention, placebo, or other control) of a clinical trial.
5 An "intervention" is defined as a manipulation of the subject or subject's environment for the purpose of modifying one or more health-related biomedical or behavioral processes and/or endpoints.
6 A "health-related biomedical or behavioral outcome" is defined as the pre-specified goal(s) or condition(s) that reflect the effect of one or more interventions on human subjects' biomedical or behavioral status or quality of life.
policy/clinical-research-policy/clinical-trials

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H. Remedies: What remedies are available for Sponsor
I. Labeling of Confidential Information: Request that Sponsor mark the disclosed information as "confidential"
J. Signatures on CDA
   a. Email signature of Designated Institutional Signatory* authorizing UConn Health to participate
   b. Email signature of Principal Investigator
   c. Sponsor's representative with signature authorization

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. Sends either partially executed or fully executed CDA to Sponsor
   g. Submits a letter to the Sponsor that describes the mandates involved in the forthcoming negotiation of the CTA
   h. Keeps computer file of fully executed CDA
C. The OCTR Fiscal Assistant is responsible for:
   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

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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:	Revised by:
Reason for revision:	
Date revised version sent to archives & current revision version # advanced:	

*See List of Institutional Signatories