

UConn Health
Office of Clinical & Translational Research
Standard Operating Procedures

Title: Essential Components of Funded Investigator Initiated Clinical Trial Agreements/CTAs	
Relates to Policy/Procedure: 303-12	
SOP#: 304-12	Version 3.0
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 identification of the essential components in an Industry Supported clinical trial/research contract for an Investigator Initiated study that is authored and to be opened by an investigator at UConn Health

Background and Significance:

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 study² in which one or more human subjects³ are prospectively assigned⁴ to one or more interventions⁵ (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

And the Institution (Sponsor) and the PI (author of the study) who may be providing:

- a) Protocol Design
- b) Intellectual Property
- c) Subjects

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).

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

UConn Health
Office of Clinical & Translational Research
Standard Operating Procedures

Title: Essential Components of Funded Investigator Initiated Clinical Trial Agreements/CTAs	
Relates to Policy/Procedure: 303-12	
SOP#: 304-12	Version 3.0
Prepared by: J. Kulko, MS, MSN	Original date: June 28, 2012
Approved by: J. Kulko, MS, MSN	Date approved: August 19, 2016

- d) Data and/or Results
- e) Publication,
- f) Input into further Intellectual Property

Scope: This SOP describes essential components of a CTA that are negotiated between the funding agency who is providing financial support for the research or other essential items (e.g. medication) and the Sponsor/Author of protocol (PI/UConn Health and the process that is used to assure accuracy and completeness. The CTA for an Investigator Initiated supported study, at a minimum must include:

- A. Scope of Work
 - a) Name of Principal Investigator, Institution (Sponsor of the Clinical Trial)
 - b) Name of company providing financial support for this Clinical Trial
 - c) Conduct of the Study
 - d) Approvals
 - e) Informed Consent
 - f) Handling and transfer of biological samples and blood
 - g) Amendments to the Protocol
 - h) Supervision of Research Staff
 - i) Subject Enrollment
- B. Records, Monitoring, Audits
 - a. Study Records
 - b. Record Retention
 - c. Access to source documentation
 - d. Reporting of Adverse Events and Serious Adverse Events
 - e. Audits by Regulatory Authorities
- C. Sponsor Obligations
 - a. Compliance with law
 - b. Drug supply, distribution and record keeping
 - c. Study registration on clinicaltrials.gov or other appropriate web site.
- D. Ownership of Data, Records and Intellectual Property
 - a. Ownership of data and records
 - b. Disclosure obligation
 - c. Ownership of inventions
 - d. License & options
 - e. Patent prosecution & cooperation
 - f. No implied license
- E. Confidentiality
 - a. Obligations & permitted exceptions

UConn Health
Office of Clinical & Translational Research
Standard Operating Procedures

Title: Essential Components of Funded Investigator Initiated Clinical Trial Agreements/CTAs	
Relates to Policy/Procedure: 303-12	
SOP#: 304-12	Version 3.0
Prepared by: J. Kulko, MS, MSN	Original date: June 28, 2012
Approved by: J. Kulko, MS, MSN	Date approved: August 19, 2016

- b. Permitted disclosures
- c. Data in source documents
- d. Confidentiality of terms
- F. Publication
 - a. Publication rights & review period
 - b. Sponsor license
 - c. Use of name
 - d. Publication list and acknowledgment
- G. Indemnification & Insurance
 - a. Indemnification including the language that UConn Health does not indemnify sponsors
 - b. "Chapter 53" language addressing Claims against the State
 - c. Industry Indemnification procedure
 - d. Insurance
- H. Representations & Covenants
 - a. Regulatory approval
 - b. Debarment
 - c. Fair Market Value
 - d. No charges to third party or subject for services or drugs/devices provided by the supporting entity
 - e. HIPAA
 - f. Power & Authority
 - g. No conflicting obligations
 - h. Institution disclosures
 - i. Conflict of Interest
- I. Term & Termination
 - a. Term
 - b. Termination by Sponsor or Institution
 - c. Termination by material breach
 - d. Procedures upon early termination
 - e. Return of property
 - f. Final accounting
 - g. Survival
- J. Miscellaneous
 - a. Remedies & Waiver
 - b. Assignment
 - c. Independent Contractor
 - d. Force Majeure

UConn Health
Office of Clinical & Translational Research
Standard Operating Procedures

Title: Essential Components of Funded Investigator Initiated Clinical Trial Agreements/CTAs	
Relates to Policy/Procedure: 303-12	
SOP#: 304-12	Version 3.0
Prepared by: J. Kulko, MS, MSN	Original date: June 28, 2012
Approved by: J. Kulko, MS, MSN	Date approved: August 19, 2016

- e. Further assurances
- f. Choice of law as being Connecticut (may be silent on this issue)
- g. Notices
- h. No third-party beneficiary
- i. Entire agreement; amendments
- j. Severability
- k. Interpretation
- K. Exhibit A
 - a. Protocol
- L. Exhibit B
 - a. Budget & payment schedule³
- M. Signatures on CTA
 - a. CTA cannot be executed until clinical trial receives at least contingent IRB approval
 - b. Contingent IRB approval is authenticated in the Integrated Research Information Systems (IRIS)
 - c. Two original CTAs must be executed
 - i. Original signature of Designated Institutional Signatory* authorizing UConn Health to participate
 - ii. Original signature of Principal Investigator
 - iii. Sponsor's representative with signature authorization

Responsibilities:

- A. The OCTR Contracts Specialist is responsible for the following:
 - a. Review, negotiation, preparation and approval of all industry sponsored clinical trials done by UConn Health faculty.
 - b. This excludes the imbedded budget which is negotiated and finalized by the Administrative and Clinical Research Coordinator.
 - c. The OCTR Contracts Specialist and the Administrative Clinical Research Coordinator each share responsibility for assuring that the correct budget is included in the CTA.
 - d. Contract check list is completed and initialed
- B. The OCTR Administrative and Clinical Research Coordinator is responsible for the following:

³ Adapted from: IOM Forum on Drug Discovery, Development & Translation; Template for CTA, Developed by Jim Snipes, Covington & Burling LLP; 2009.
www.iom.edu/~media/Files/.../Research/.../TemplateCTA%2042209.ashx

UConn Health
Office of Clinical & Translational Research
Standard Operating Procedures

Title: Essential Components of Funded Investigator Initiated Clinical Trial Agreements/CTAs	
Relates to Policy/Procedure: 303-12	
SOP#: 304-12	Version 3.0
Prepared by: J. Kulko, MS, MSN	Original date: June 28, 2012
Approved by: J. Kulko, MS, MSN	Date approved: August 19, 2016

- a. Negotiating the budget and relaying any pertinent information to the Contract Specialist
 - b. Reviewing budget in final contract to assure that the contract includes the correct version of the budget and signing off and dating the final paper copy and scanning a copy for the electronic file
 - c. Reviewing the consent, sponsor budget and Budget Workbook to assure consistency between the three documents relative to which services are routine care paid by insurance and which are protocol induced and paid by sponsor.
- C. The OCTR Fiscal Administrator is responsible for the following:
- a. Recording completion dates in Access

Procedural Steps:

The OCTR Contracts Specialist completes the following steps:

- A. Reviews new contract for completeness and language that is acceptable to PI, Institution and State of Connecticut. This includes language governing:
 - a. Indemnification and Chapter 53 language
 - b. Insurance
- B. Redlines agreement to make necessary revisions
- C. Negotiates with the Sponsor/CRO until contract agreement is reached
- D. Requests clean copy of the agreement incorporating agreed upon changes
 Reviews clean copy of the agreement to ensure its accuracy and to record completion date of contract
- E. Initials completed contract check list

The OCTR Administrative & Clinical Research Coordinator completes the following steps:

- A. Signs off and dates final budget
- B. Adds final budget to the contract

Revision date: 8/19/16; 1/28/14	Revised by: J. Kulko
Reason for revision: 3.0 Reflect changes in system; name change 2.0 Reflect changes in system	
Date revised version sent to archives & current revision version # advanced: 8/19/16	

*See List of Institutional Signatories