UConn Health
Office of Clinical & Translational Research
Standard Operating Procedures

Title: Essential Components of Clinical Trial Agreements/CTA (Sponsored by Industry)	
Relates to Policy/Procedure: 300-12	
SOP#: 302-12	Version 5.0
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 and inclusion of the essential components necessary in an Industry Sponsored contract for a Clinical Trial that is to be opened by investigators 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 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

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

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[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

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Scope: This SOP describes essential components of a CTA that are negotiated between an Industry sponsor and UConn Health and the process that is used to assure accuracy and completeness. If the sponsor and the contract specialist in the OCTR cannot agree on the terms and conditions of the agreement, the Executive Administrator of the OCTR, the Associate Dean of Clinical Research Planning & Coordination, the Associate Vice President Sponsored Programs and Services, and the UConn Health PI will be notified of the impasse in contract negotiations. If no consensus can be reached regarding the terms and conditions in question, the contract will be submitted to the General Counsel for an opinion regarding said terms and conditions.

The CTA, at a minimum must include:

A. Sponsor Name
B. Scope of Work
    a) Name of Principle Investigator, Institution
    b) Conduct of the Study
    c) Approvals
    d) Informed Consent
    e) Handling and transfer of biological samples and blood
    f) Amendments to the Protocol
    g) Supervision of Research Staff
    h) Subject Enrollment
C. Records, Monitoring, Audits
    a. Study Records
    b. Record Retention
    c. Access to source documentation
    d. Reporting of Adverse Events and Serious Adverse Events
    e. Monitoring by sponsor/contract research organization (CRO)
    f. Audits by Regulatory Authorities
D. Sponsor Obligations
    a. Compliance with law
    b. Drug supply, distribution and record keeping
    c. Subject Injury including reference to Medicare second payor rule that Medicare must be the second payor and as such cannot be bill for patient injury services that have already been billed and rejected by insurance (non-Medicare/Medicaid)[i]
    d. Study registration
E. 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

F. Confidentiality
   a. Obligations & permitted exceptions
   b. Permitted disclosures
   c. Data in source documents
   d. Confidentiality of terms

G. Publication
   a. Publication rights & review period
   b. Multi-Center publication & review period
   c. Sponsor license
   d. Use of name
   e. Publication list and acknowledgment

H. Indemnification & Insurance
   a. Indemnification including the state of Connecticut language that we do not indemnify sponsors, & "Chapter 53" language
   b. Indemnification procedure
   c. Insurance

I. Representations & Covenants
   a. Regulatory approval
   b. AAHRPP language relating to 5 essential elements required by AAHRPP including:
      i. Subject injury language
      ii. Prompt reporting from the sponsor to the PHI and to the IRB any finding that could influence the conduct of the study, alter the IRB's approval to continue the study, or that relates to subject safety and/or could influence subject's willingness to continue participation. For purposes of this policy prompt is considered within 30 days of sponsor becoming aware of information.
      iii. Prompt reporting to the PI and IRB outcomes and/or recommendations of Data Safety Monitoring Board per DSMB charter.
      iv. Publication language defining organization's right to publish
      v. Prompt reporting to the Institution late adverse events or serious adverse events that may impact subjects for at least two years after

study closure[ii]. Communication from sponsor to be sent to PI of study and IRB office.

Note: UConn Health will demonstrate good faith efforts to execute contracts that commit the sponsor to obligations and the time frames noted above; however in negotiations with sponsors, while elements will not be waived in entirety, reasonable exceptions may be made to specifics (e.g. accepting a 90 day reporting requirement, accepting sponsors commitment to report information for active studies to PI, when internal policies then commit PI to report information to IRB within 5 days).

c. Debarment
d. Fair Market Value
e. No charges to third party or subject for services or drugs/devices provided by sponsor
f. HIPAA
g. Power & Authority
h. No conflicting obligations
i. Institution disclosures
j. Conflict of Interest

J. 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

K. Miscellaneous
   a. Remedies & Waiver
   b. Assignment
   c. Independent Contractor
   d. Force Majeure
   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

L. Exhibit A
   a. Protocol

M. Exhibit B
   a. Budget & payment schedule[3]

N. Signatures on CTA
   a. CTA cannot be executed until clinical trial receives as least contingent IRB approval
   b. This must be authenticated through the Integrated Research Information Systems (IRIS)r
   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. Reviewing, 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.

B. The OCTR Administrative and Clinical Research Coordinator is responsible for the following:
   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

[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/.../**Template**CTA%2042209.ashx

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

A. New contract is reviewed 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. Negotiations with the Sponsor/CRO until agreement is reached
C. Changes are made and redline version is sent to Sponsor/CRO
D. Returned document is reviewed for accuracy by UConn Health Contracts Specialist and date noted when contract is complete
E. Administrative & Clinical Research Coordinator signs off and dates final budget
F. Final budget is added to the contract
G. Date noted when contract and budget are complete
H. Contract check list is completed and initialed

[i] **Note: minimal risk studies including registries do not require subject injury language**
[ii] **Note: registries do not require all elements of AAHRPP language**

Revision date: 8/19/16; 2/27/14; 8/2/13; 1/16/13	Revised by: D. Clavette
Reason for revision: 5.0 Reflect procedure changes; name change 4.0 Refelect procedure changes 3.0 Update AAHRPP requirements and negotiation process with sponsor 2.0 Update text regarding sponsor negotiations	
Date revised version sent to archives & current revision version # advanced: 8/19/16	

*See List of Institutional Signatories