UConn Health
Office of Clinical & Translational Research
Standard Operating Procedures

Title: Essential Components of a University to University Agreement/Subcontract	
Relates to Policy/Procedure: 306-12	
SOP#: 307-12	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 identification and inclusion of the essential components necessary in a University to University Agreement for a Clinical Trial that is to be opened by investigators at UConn Health. A University to University Agreement is a subcontract between UConn Health and another University "University" for a clinical trial; the other University has an agreement with a Sponsor, or the clinical trial is financially supported by a company within industry who may also be providing the investigational drug or device, such as a pharmaceutical company. UConn Health is not a party to the contract with the Sponsor.* University to University Agreements will be herein referred to as "University Subcontract."

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

[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

Title: Essential Components of a University to University Agreement/Subcontract	
Relates to Policy/Procedure: 306-12	
SOP#: 307-12	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

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 SOP describes essential components of a University Subcontract that are negotiated between a University and UConn Health and the process that is used to assure accuracy and completeness. The University Subcontract, at a minimum must include:

A. Name University with whom the subcontract is executed and includes:
   a. the Industry Sponsor who authored the clinical trial
   b. Company within Industry who is providing financial support or providing the investigational drug or device
B. Scope of Work
   a) Name of Principal 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 University
   f. Audits by Regulatory Authorities
D. University 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 billed for patient injury services that have already been billed and rejected by insurance (non-Medicare/Medicaid)[i]

Title: Essential Components of a University to University Agreement/Subcontract	
Relates to Policy/Procedure: 306-12	
SOP#: 307-12	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

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. Reporting by sponsor to organization any monitoring findings relating to subject safety and influence his/her willingness to continue participation
      iii. Reporting to IRB outcomes and/or recommendations of Data Safety Monitoring Board per DSMB charter
      iv. Publication language defining organization's right to publish
      v. Reporting to the Institution late adverse events or serious adverse events that may impact subjects[ii]
   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 University Subcontract
a. University Subcontract cannot be executed until clinical trial receives as least contingent IRB approval

[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

Title: Essential Components of a University to University Agreement/Subcontract	
Relates to Policy/Procedure: 306-12	
SOP#: 307-12	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

b. This must be authenticated through the Integrated Research Information Systems (IRIS)Two original University Subcontracts 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, and approval of all university to university clinical trials done by UConn Health faculty that are done under a sub contract with another University. This includes:
      i. Studies for which there is an Industry Sponsor
      ii. Studies for which the University is the Sponsor but the study is financially supported by a company within Industry and/ or is providing investigational drug or the device to be used in the clinical trial
   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 University Subcontract.

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

Title: Essential Components of a University to University Agreement/Subcontract	
Relates to Policy/Procedure: 306-12	
SOP#: 307-12	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

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 University/Sponsor until agreement is reached
C. Changes are made and redline version is sent to University/Sponsor
D. Returned document is reviewed for accuracy by OCTR Contracts Specialist and date noted when University Subcontract is complete
E. Administrative & Clinical Research Coordinator signs off and dates final budget
F. Final budget is added to the University Subcontract
G. Date noted when University Subcontract and budget are complete
H. University Subcontract 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 AAHRPP language**
***UCHC may be a party to an ancillary agreement with the Sponsor, such as agreements concerning indemnification.**
****Note: Subject Injury language not commonly stated in University Subcontracts; the inclusion of Subject Injury language is contingent upon the clinical trial being sponsored by Industry rather than funded by Industry.**

Revision date: 8/19/16	Revised by: D. Clavette
Reason for revision: Reflect changes to procedures; name change	
Date revised version sent to archives & current revision version # advanced: 8/19/16	

*See List of Institutional Signatories