

UConn Health
Office of Clinical & Translational Research
Standard Operating Procedures

Title: Execution of University to University Subcontracts	
Relates to Policy/Procedure: 304-12	
SOP#: 306-12	Version 4.0
Prepared by: J. Kulko, MS, MSN	Original date: June 28, 2012
Approved by: J. Kulko, MS, MSN	Date approved: October 6, 2016

Purpose and Applicability: The purpose of this document is to establish a uniform process for the preparation, review, negotiation and approval of all University to University clinical trials/research contracts. A University to University agreement, is a subcontract between UConn Health and another 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: No SOP’s exist at UConn Health that describe the overall procedure governing the preparation, review and approval of University Subcontracts. A centralized approach to University Subcontract negotiation and ultimate approval, which includes the University Subcontract and imbedded budget, was deemed necessary to accurately and consistently negotiate contracts in a timely manner. This centralized approach is also needed to monitor the progress of these contracts and to assess the amount of time required to complete the contract process.

Scope: This SOP describes the steps followed by the Researcher, University, OCTR staff, and at times the Sponsor/company providing financial support, or the investigational agent or device to execute a clinical trial/research agreement in a timely manner for a University Subcontract. The “essential components” of a clinical trial contract are not included in this procedure but can be found in SOP 307-12.

Responsibilities:

- A. The OCTR Contracts Specialist is responsible for the negotiation of all industry supported clinical research/trials done by UConn Health faculty. The process includes:
 - a. Reviewing all contracts
 - b. Revising University Subcontract language and drafting necessary language
 - c. Negotiating proposed University Subcontract revisions with University or Sponsor /company providing financial support or the investigational agent or device
 - d. Contacting PI regarding University Subcontract language
 - e. Seeking an opinion from Assistant Attorney General/General Counsel, if needed
 - f. Confirming budget information with Administrative & Clinical Research Coordinator who completes budget workbooks and negotiates the budget

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- g.** Signing the contract and budget Approval form
- h.** Accepting final version of the University Subcontract
- i.** Obtaining signatures from UConn Health’s Designated Institutional Signatory**, Principal Investigator and the University when at least IRB contingent approval is confirmed through the Integrated Research Information System (IRIS).
- j.** Rendering signed University Subcontract to Fiscal Assistant to FedEx/UPS back to University for signature

B. The OCTR Fiscal Assistant is responsible for the following:

- a.** Constructing Access files to include a list of all new contracts and the status of contracts under negotiation
- b.** Obtaining tax ID number from Sponsor, if a new Sponsor
- c.** Distributing copies of contracts including budgets to Administrative and Clinical Research Coordinator
- d.** Contacting University Sponsor regarding status of contracts
- e.** Informing UConn Health Investigator of the status of contracts
- f.** Obtaining signatures from UConn Health Investigator and Designated Institutional Signatory**
- g.** Obtaining FedEx/UPS number from University (or using our own account if necessary) Sending University Subcontracts (FedEx/UPS) (Contracts are never sent in regular mail)
- h.** Recording date executed University Subcontract received back from sponsor
- i.** Sending copy of fully executed University Subcontract to the study coordinator and the PI
- j.** Obtaining completed Institutional Routing form
- k.** Removing University Subcontract from active list after receiving IRB approval letter
- l.** Giving original signed University Subcontract to Reimbursement Analyst
- m.** Maintaining paper and electronic files (on OCTR I drive) of all completed contracts

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

- a.** Performing Medicare analysis to assess status as a Medicare Qualifying Trial per National Coverage Decision of 2000 together with the Coding Reimbursement Specialist

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- b. Negotiating the budget and relaying any pertinent information to the Contracts Specialist
- c. Reviewing the budget in final University Subcontract to assure it is the correct version of the budget by signing off and dating the final paper copy and putting a scanned copy in the electronic file
- d. Signing the budget and contract Approval form
- e. 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.

D. The OCTR Reimbursement Analyst is responsible for the following:

- a. Setting up the new Banner fund in the system
- b. Setting up companion cost sharing account in Banner if needed
- c. Setting up Co-operative group sub-account in Banner if needed
- d. Calculating and loading the initial budget in Banner

Procedural Steps (Research Team):

- A. Researcher and/or research team sends proposed agreement to the Contracts Specialist in OCTR via e-mail
 - a. This must include proposed budget, protocol and grant and current consent

Procedural Steps (OCTR staff):

These procedural steps are done by the appropriate OCTR staff:

OCTR Fiscal Administrator:

- a. Enters new University Subcontract into Access, including date received
- b. Obtains Tax ID from the University (if a new University)
- c. Sends copy of University Subcontract with budget, protocol/grant and current consent to OCTR Administrative and Clinical Research Coordinator and OCTR Contracts Specialist

OCTR Contracts Specialist:

- a. Reviews the original University Subcontract
- b. Redlines University Subcontract and makes changes to the University Subcontract to ensure compliance with institutional state and federal regulations and guidance
- c. Negotiates agreement with University/Sponsor Reviews and accepts final University Subcontract, including budget

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- d. Signs the budget and contract Approval form
- e. Confirms at least contingent approval through IRIS.
- f. Obtains Signature of Designated Institutional Signatory** and PI

OCTR Administrative and Clinical Research Coordinator:

- a. Performs Medicare analysis
- b. Negotiates budget and incorporates changes into the University Subcontract
- c. Reviews and accepts the final budget and confirms this with OCTR Contracts Specialist
- d. Signs the budget and contract Approval form

OCTR Fiscal Administrator:

- a. Obtains FedEx/UPS number from University (or use our own account if necessary)Sends cover letter with our correct address (including mail code) and W-9 to University with 2 or 3 originals of executed contract (depending if the Sponsor or the company providing financial support needs an original)
- b. Sends documents via FedEx/UPS (never send by regular mail)
- c. Tracks status of University Subcontract Informs PI of status
- d. Notes date in Access when fully executed University Subcontract is received from University as project completion date
- e. Sends fully executed University Subcontract to IRB administrator only if there is subject injury language to review.
- f. Files paper copy of fully executed University Subcontract and sets up electronic file in OCTR I drive
- g. Removes University Subcontract from active list when IRB final approval letter is received and notes date in Access
- h. Gives fully executed University Subcontract to Reimbursement Analyst

OCTR Reimbursement Analyst:

- a. Sets up the new Banner fund in the system
- b. Sets up companion cost sharing account in Banner if needed
- c. Sets up Co-operative group sub-account in Banner if needed
- d. Calculates and loads the initial budget in Banner

*UConn Health may be a party to an ancillary agreement with the Sponsor, such as agreements concerning indemnification.

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**See List of Institutional Signatories