UConn Health
Office of Clinical & Translational Research
Standard Operating Procedures

Title: Execution of Industry Sponsored Clinical Trial Contracts	
Relates to Policy/Procedure:300-12;302-12	
SOP#: 301-12	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 review, negotiation, preparation and approval of all Industry sponsored clinical trials contracts between UConn Health and an Industry sponsor.

Background and Significance: No SOPs exist at UConn Health that describes the overall procedure governing the review, negotiation, preparation and approval of Industry Sponsored clinical trials contracts. A centralized approach to contract negotiation and ultimate approval, which includes the contract 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 produce a realistic assessment of the time it takes to successfully complete contract negotiations.

Scope: This SOP describes the steps to be followed by the Researcher, Sponsor and the OCTR staff to execute a clinical trial agreement in a timely manner for an Industry Sponsored Clinical Trial. The "essential components" of a clinical trials contract is not included in this procedure but can be found in SOP 302-12.

Responsibilities:

A. The OCTR Contracts Specialist is responsible for the negotiation of all industry sponsored clinical trials done by UConn Health faculty. The process includes:

- **a.** Reviewing all contracts
- **b.** Revising contract language and drafting necessary language
- **c.** Negotiating proposed contract revisions with Sponsor or CRO
- **d.** Contacting PI regarding contract language for opinion and approval
- **e.** Seeking an opinion from Assistant Attorney General/General Counsel , if needed
- **f.** Confirming budget information with the OCTR Administrative & Clinical Research Coordinator who completes budget workbooks and negotiates the budget
- **g.** Accepting final version of contract
- **h.** Sending copy of "subject injury language" if appropriate to study coordinator
- **i.** Obtaining signatures from UConn's Designated Institutional Signatory* and the PI, upon contingent IRB approval (confirmed in the Integrated Research Information Systems, IRIS.)

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j. Rendering signed contract to Fiscal Assistant to FedEx/UPS back to Sponsor for signature

B. The OCTR Fiscal Assistant in the OCTR 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 and consent to Administrative and Clinical Research Coordinator
- **d.** Contacting Sponsor/CRO 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 Sponsor/CRO
- **h.** Sending contracts (FedEx/UPS) (Contracts are never sent in regular mail)
- **i.** Recording date executed contract received back from sponsor
- **j.** Sending copy of fully executed contract to study coordinator and the PI
- **k.** Obtaining completed Institutional Routing Sheet
- **l.** Removing contract from the active list after receiving IRB approval letter
- **m.** Giving original signed contract to Reimbursement Analyst
- **n.** 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 OCTR Coding Reimbursement Specialist
- **b.** Negotiating the budget and relaying any pertinent information to the Contract Specialist
- **c.** Obtaining PI approval of budget in writing
- **d.** Reviewing the budget in final contract 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
- **e.** Initialing the final budget and putting a scanned copy in the electronic file
- **f.** 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 Coding Reimbursement Specialist is responsible for:
- **a.** Identifying the routine care costs of a qualifying clinical trial which will require a clinicaltrials.gov NCT number affixed to the Medicare charges
- **b.** Confirming Protocol Induced Costs to be paid ty sponsor
- **c.** Confirming routine medical costs not related to the clinical trial which will not require NCT number

E. 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

I. Procedural Steps (Research Team):

A. Researcher and/or research team sends proposed agreement to the Contract Specialist or Administrative and Clinical Research Coordinator in OCTR via e-mail
- **a.** This must include proposed budget, protocol, contract and current consent

II. Procedural Steps (OCTR Staff): These procedural steps are done by the appropriate OCTR staff:

B. OCTR Fiscal Administrator:
- **a.** Enters new CTA into Access, including date received
- **b.** Obtains Tax ID from the Sponsor, (if a new Sponsor)
- **c.** Sends copy of contract with budget, protocol/contract and current consent to OCTR Administrative and Clinical Research Coordinator and UConn Contracts Specialist

C. OCTR Contracts Specialist:
- **a.** Reviews the original CTA

b. Redlines CTA and makes changes to the CTA to ensure compliance with institutional state and federal regulations and guidance
c. Negotiates agreement with Sponsor/CRO
d. Reviews and accepts final contract, including budget by signing off on contract/budget approval form
e. Confirms in the IRIS system that the clinical trial has at least contingent IRB approval.
f. Obtains Signature of Designated Institutional Signatory* and PI

D. OCTR Administrative and Clinical Research Coordinator:
a. Completes Medicare analysis with the Coding Reimbursement Specialist
b. Negotiates budget and incorporates changes into the contract
c. Obtains PI budget approval in writing
d. Reviews and accepts the final budget and confirms this with the OCTR Contract Specialist by signing off on contract/budget approval form

E. OCTR Coding Reimbursement Specialist:
a. Assesses status of the clinical trial as a Medicare qualifying clinical trial under the 2000 NCD with the Administrative and Clinical Research Coordinator
b. Identifies the routine care costs associated with the clinical trial which will require a clinicaltrials.gov NCT number affixed to the Medicare charges
c. Confirms the PIC to be paid by the sponsor
d. Confirms the routine medical services not related to the protocol

F. OCTR Fiscal Administrator:
a. Obtains FedEx/UPS number from Sponsor/CRO
b. Sends cover letter with our correct address (including mail code) and W-9 to Sponsor with 2 or 3 originals of executed contract (depending if CRO needs an original)
c. Sends documents via FedEx/UPS (never send by regular mail)
d. Tracks status of CTA
e. Informs PI of status
f. Notes date in Access when fully executed CTA is received from Sponsor/CRO as project completion date
g. Sends fully executed contract to study coordinator and PI
h. Includes completed Institutional Routing Sheet in contract packet

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i. Obtains an InfoEd number
j. Obtains a BEAN number
k. Emails Clinical Initiation Form to appropriate people
l. Files paper copy of fully executed CTA and sets up electronic file in OCTR I drive
m. Removes contract from active list when IRB final approval letter is received and notes date in Access
n. Gives fully executed contract to Reimbursement Analyst

G. OCTR Reimbursement Analyst:
a. Obtains a Banner account number
b. Sets up the new Banner fund in the system
c. Sets up companion cost sharing account in Banner if needed
d. Set up Co-operative group sub-account in Banner if needed
e. Calculates and loads initial budget in Banner

Revision Date: 10/6/16; 8/19/16; 10/17/14
4.0 SOP Updated to remove full board approval for minimal risk studies approved through expedited review. 3.0 Update procedure; name change 2.0 Update procedure
Date revised version sent to archives & current revision version # advanced: 10/6/16

*See List of Institutional Signatories