# UConn Health
## Office of Clinical & Translational Research
## Standard Operating Procedures

| Title: Execution of Industry Funded Investigator Initiated Contracts | |
|---|---|
| Relates to Policy/Procedure: 302-12 | |
| SOP#: 303-12 | Version 5.0 |
| Prepared by: D. Clavette | Original date: June 28, 2012 |
| Approved by: P. Hudobenko | Date approved: June 30, 2018 |

**Purpose and Applicability:** The purpose of this document is to establish a uniform process for the preparation, review; negotiation and approval of all Investigator Initiated Industry Supported clinical trials/research contracts.

**Background and Significance:** No SOP's exist at UConn Health that describes the overall procedure governing the preparation, review and approval of Industry Funded clinical research/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 assess the amount of the time required to complete the contract process.

**Scope:** This SOP describes the steps followed by the Researcher, Sponsor and OCTR staff to execute a clinical trial/research agreement in a timely manner for an Investigator Initiated Industry Funded Clinical Trial/Research. The "essential components" of a clinical trial contract are not included in this procedure but can be found in SOP 304-12.

**Responsibilities:**

**A.** The OCTR Contracts Specialist is responsible for the negotiation of all industry supported clinical research/trials done by the 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
- **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
- **g.** Accepting final version of contract
- **h.** Signing the contract and budget Approval form
- **i.** Obtaining signatures from UConn's Designated Institutional Signatory*, Principal Investigator and Sponsor when at least IRB contingent approval is confirmed through the Integrated Research Information Systems (IRIS).
- **j.** Emailing signed contract to to Sponsor for signature

| Title: Execution of Industry Funded Investigator Initiated Contracts | |
|---|---|
| Relates to Policy/Procedure: 302-12 | |
| SOP#: 303-12 | Version 5.0 |
| Prepared by: D. Clavette | Original date: June 28, 2012 |
| Approved by: P. Hudobenko | Date approved: June 30, 2018 |

**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 Sponsor/CRO regarding status of contracts
- **e.** Informing the UConn Health Investigator of the status of contracts
- **f.** Obtaining signatures from the UConn Health Investigator and Designated Institutional Signatory*
- **g.** Recording date executed contract received back from sponsor
- **h.** Sending copy of fully executed contract to the study coordinator and PI
- **i.** Obtaining completed Institutional Routing form
- **j.** Removing contract from active list after receiving IRB approval letter
- **k.** Giving original signed contract to Reimbursement Analyst
- **l.** 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.** Signing the budget and contract Approval form
- **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

| Title: Execution of Industry Funded Investigator Initiated Contracts | |
|---|---|
| Relates to Policy/Procedure: 302-12 | |
| SOP#: 303-12 | Version 5.0 |
| Prepared by: D. Clavette | Original date: June 28, 2012 |
| Approved by: P. Hudobenko | Date approved: June 30, 2018 |

**b.** Confirming Protocol Induced Costs to be paid by 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 and grant and current consent

## II. Procedural Steps (OCTR staff):

These procedural steps are done by the appropriate OCTR staff:

**B.** The 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/grant and current consent to OCTR Administrative and Clinical Research Coordinator and the OCTR Contracts Specialist
**d.** Obtains an InfoEd number
**e.** Emails Clinical Initiation Form to appropriate people

**C.** The 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
**e.** Signs budget and contract Approval form
**f.** Confirms through the IRIS system that that the clinical trial has at least contingent approval.

| Title: Execution of Industry Funded Investigator Initiated Contracts | |
|---|---|
| Relates to Policy/Procedure: 302-12 | |
| SOP#: 303-12 | Version 5.0 |
| Prepared by: D. Clavette | Original date: June 28, 2012 |
| Approved by: P. Hudobenko | Date approved: June 30, 2018 |

**g.** Obtains Signature of Designated Institutional Signatory* and PI

**D.** The OCTR Administrative and Clinical Research Coordinator:
- **a.** Performs Medicare analysis together with the Coding Reimbursement Specialist
- **b.** Negotiates budget and incorporates changed into the contract
- **c.** Reviews and accepts the final budget and confirms this with OCTR Contracts Specialist
- **d.** Signs the budget and contract Approval form

**E.** The OCTR Fiscal Administrator:
- **a.** Tracks status of CTA
- **b.** Informs PI of status
- **c.** Notes date in Access when fully executed CTA is received from Sponsor/CRO as project completion date
- **d.** Sends fully executed contract to study coordinator and PI
- **e.** Includes completed Institutional Routing form with contract packet
- **f.** Files paper copy of fully executed CTA and sets up electronic file in OCTR I drive
- **g.** Removes contract from active list when IRB final approval letter is received and notes date in Access
- **h.** Gives fully executed contract to Reimbursement Analyst

**F.** The 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

# UConn Health
## Office of Clinical & Translational Research
## Standard Operating Procedures

| Title: Execution of Industry Funded Investigator Initiated Contracts | |
|---|---|
| Relates to Policy/Procedure: 302-12 | |
| SOP#: 303-12 | Version 5.0 |
| Prepared by: D. Clavette | Original date: June 28, 2012 |
| Approved by: P. Hudobenko | Date approved: June 30, 2018 |

| Revision date: 6/30/18; 10/6/16; 8/19/16; 1/17/14 Revised by: P. Hudobenko |
|---|
| Reason for revision:<br>5.0 Update to remove use of FedEx/UPS for contract.<br>4.0 SOP Updated to remove full board approval for minimal risk studies approved through expedited review<br>3.0 To reflect current procedures; name change<br>2.0 To reflect current procedures |
| Date revised version sent to archives & current revision version # advanced:6/30/18 |

*See List of Institutional Signatories