UConn Health
Office of Clinical & Translational Research
Standard Operating Procedures

Title: Execution of Industry Sponsored Clinical Trial Contracts for Dermatology Studies with Probity as a Business Associate	
Relates to Policy/Procedure:300-12;302-12	
SOP#: 308-12	Version 4.0
Prepared by: D. Clavette	Original date: July 26, 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 review, negotiation, preparation and approval of all Industry sponsored dermatological clinical trials contracts between UCONN HEALTH and an Industry sponsor, with Probity Medical Research Corp. herein "PMR" as a fiscal agent, and, at times, a party to the contract.

Background and Significance: No SOP exists at UConn Health that describes the overall procedure governing the review, negotiation, preparation and approval of Industry Sponsored dermatological clinical trials contracts with PMR as a fiscal agent. 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, PMR, and 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 are not included in this procedure but can be found in SOP 302-12 and essential components of a Subcontract can be found in 307-12.

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
- **e.** Seeking an opinion from Assistant Attorney General, if needed
- **f.** Confirming budget information with Administrative & Clinical Research Coordinator who completes budget workbooks
- **g.** Signing the budget and contract Approval form
- **h.** Accepting final version of contract
- **i.** Sending copy of "subject injury language" if appropriate to Study coordinator

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j. Obtaining signatures from UConn Health's Designated Institutional Signatory** and the PI, when contingent approval is authenticated through the Integrated Research Information Systems (IRIS.
k. Rendering signed contract to Fiscal Assistant to email back to Probity*; Probity will sign and then forward the agreement to the Sponsor/CRO 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 the source of revenue, if a new (Sponsor/CRO)
- **c.** Distributing copies of contracts including budgets 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**
  - **i.**
- **g.** Recording date executed contract received back from sponsor
- **h.** Sending copy of fully executed contract to study coordinator and PI
- **i.** Removing contract from the active list after receiving IRB approval letter
- **j.** Giving original signed contract to Reimbursement Analyst
- **k.** 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.** Completing budget workbook and sending information to PI. N.B. **Probity negotiates budget and sends final budget to OCTR.**
- **b.** Reviewing the budget in final contract to assure it is the correct version of the budget by initialing and dating the final paper copy and putting a scanned copy in the electronic file
- **c.** Signing the budget and contract Approval form
- **d.** Reviewing the consent, sponsor budget and Budget Workbook to assure consistency among 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.** Establishing a Banner account
- **b.** Developing a working budget within the account
- **c.** Subsidizing account

Procedural Steps (Research Team):

A. Researcher and/or research team sends proposal to the Contract Specialist and/or Administrative and Clinical Research Coordinator 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. New CTA is entered into Access database, including date received
b. Tax ID number is obtained from the Sponsor/CRO (if a new Sponsor)
c. Copy of contract including budget, protocol and current consent is sent to OCTR Administrative and Clinical Research Coordinator and OCTR Contracts Specialist

OCTR Contracts Specialist:
a. Original CTA is reviewed
b. Appropriate changes made to the CTA to meet institutional and state regulations and guidelines
c. Changes in contract negotiated with Sponsor/CRO
d. Revisions sent to Sponsor/CRO
e. New Sponsor/CRO revisions reviewed
f. Budget information confirmed with Administrative & Clinical Research Coordinator who completes budget workbooks
g. Budget and contract Approval form signed
Contingent IRB approval is authenticated in IRIS.
h. Signature of Designated Institutional Signatory** and PI obtained

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OCTR Administrative and Clinical Research Coordinator:

a. Budget Workbook is complete and final budget is sent to Probity and PI
b. Budget revisions reviewed
c. Sign off for final budget by Administrative and Clinical Research Coordinator by initialing and dating the final paper copy and putting a scanned copy in the electronic file
d. Signs the budget and contract Approval form

Probity:

a. Probity negotiates the research budget and sends final to OCTR

OCTR Fiscal Administrator:

a. Status of CTA tracked
b. PI informed of status
c. Date fully executed CTA is received from Sponsor/CRO is noted in Access as project completion date
d. Fully executed contract is sent to Study coordinator and PI
e. Paper copy of fully executed CTA is filed and electronic file is set-up in OCTR I drive
f. Contract is removed from the active list when IRB final approval letter is received and date noted in Access.
g. Fully executed contract given to Reimbursement Analyst
h. Obtains an InfoEd number
i. Sets up Budget Initiation Meeting for Clinical TrialEmails Clinical Initiation Form to appropriate people

OCTR Reimbursement Analyst:

a. Establishes Banner account
b. Develops working budget within the account
c. Subsidizes account

* UConn Health will send contract directly to Probity, only when Probity is a signatory on the agreement. When Probity is not a signatory, the contract will be sent via email directly to the Sponsor/CRO.

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Revision date: 6/30/18; 10/6/16; 8/19/16 Revised by: P. Hudobenko
Reason for revision: 4.0 Update to remove use of FedEx/UPS for contract and delete use of BEAN number 3.0 SOP Updated to remove full board approval for minimal risk studies approved through expedited review 2.0 Reflect changes to procedure; name change
Date revised version sent to archives & current revision version # advanced: 6/30/18

**See List of Institutional Signatories