SOP Number	*ADM-009-01*
SOP Name	*Commercially Sponsored Clinical Trials Process SOP*
Effective Date	*01/SEP/2012*

1.0 SCOPE

1.1 All proposals to or from commercial entities to fund clinical trials taking place in UC Health facilities or utilizing UC Health resources must be processed through the Clinical Trials Office and compliant with the following guidelines.

2.0 PURPOSE

2.1 The procedures described below involve an in depth budgetary, administrative and legal review of the proposals and resulting contracts.

2.2 These guidelines are applicable to all commercially sponsored clinical trials performed by UC Health Investigator(s) or Principal Investigator(s). “Clinical Trials”, a “Study”, or “Studies” for the purpose of this document are defined as any investigation involving human subjects or human tissue samples. All such trials (except material transfer agreements that are processed through UC Health/UC legal counsel) require review and approval by an Institutional Review Board (IRB) consistent with the UC IRB policies and procedures.

2.3 Studies funded by government sources such as the National Institutes of Health (NIH), foundations, officially recognized not-for-profit entities such as American Heart Association (AHA), and academic institutions must be routed through the University of Cincinnati Sponsor Research Services (SRS) according to their guidelines http://www.srs.uc.edu/. In these cases, SRS and the CTO may work together to assure that appropriate expertise is brought to bear on a particular Study.

2.4 Studies with unclear funding (academic institutions with industry as the prime source) or mixed funding (both federal and industry support) will require assignment to either the CTO or SRS and PIs should contact one of these departments/divisions for assistance.

3.0 DEFINITIONS

3.1 **Confidentiality Disclosure Agreement (CDA):** is a legal document between the sponsor company (“Sponsor”) and/or contract research organization (“CRO”) and University of Cincinnati Physicians Company, LLC (UCPC, LLC) (“Institution”) to protect confidential information. Upon receipt of an executed CDA, the Sponsor/CRO and Institution can exchange any pertinent documents or information for review.

3.2 **Clinical Trial Agreement (CTA):** is the legally binding agreement between a sponsor and an institution (site) as to how certain business and property rights will be dealt with between the parties. These agreements are separate from Investigator Agreements and Confidentiality Agreements and are not regulated by FDA or disclosable to FDA. CTAs are important because they allocate risk, responsibility, financial support, and obligations of the parties; and they protect the rights of the parties.

3.3 **Amendment:** to a CTA is a contract modification. It may introduce or cancel specifications of terms of the existing, underlying contract, while leaving intact the CTAs overall purpose and effect. Most CTA amendments address changes to the budgets that were attached as exhibits to the original

trial agreement. All CTA amendments must be in writing and submitted to CTO for review and negotiation.

4.0 PROCEDURES

4.1 The CTO Cover Sheet should be submitted with each CDA, CTA, and/or Amendment.

4.2 A CTO ID number will be assigned to new studies. The CTO ID number will be consistent for all documents associated with the study.

4.3 Confidentiality Disclosure Agreement (CDA)

4.3.1 A CDA must be executed prior to any exchange of information between UC Health and a commercial sponsor or their designated representative.

4.3.2 Every attempt is made to execute a mutual CDA to protect sponsor and institutional confidential information.

4.3.3 The CDA must be signed by a person with institutional signatory authority.

4.3.3.1 CTO Director or Clinical Trials Administrator

4.3.3.2 Vice President Research

4.3.3.3 Chief Executive Officer

4.3.3.4 Chief Legal Counsel

4.3.4 Principal Investigators or departmental/division signatory authorities are not permitted to sign on behalf of the institution.

4.3.5 The CTO Contracts Coordinator is responsible for initiating, reviewing, facilitating and finalizing the CDA. The targeted timeline for initial response to sponsor is within 48 hours with follow up with sponsor if no response in 10 business days.

4.3.6 Once the CDA is fully executed the PI and department/division contact (as indicated on the CTO Cover Sheet) will be notified.

4.3.7 The final PDF version of the document will be maintained by the CTO. Any originals will be sent to the department/division for filing with study documents.

4.3.8 All CDAs will be tracked in the CTO operations database including the date of execution.

4.3.9 The department/division is responsible for obtaining a final protocol, Clinical Trial Agreement and proposed budget from the Sponsor.

4.4 Clinical Trial Agreement (CTA)

4.4.1 The CTO Contracts Coordinator is responsible for facilitating legal review and approval of the CTA. The targeted timeline for submission to legal is within 48 hours with initial

response to sponsor within 10 business days and follow up with sponsor if no response in 10 business days.

4.4.2 The CTA must be signed by a person with institutional signatory authority for UCPC, LLC (as defined above in 4.3.3) and (when applicable) a person with departmental/division signatory authority as listed below.

4.4.2.1 Department Chair

4.4.2.2 Executive Director, Business Administration (EDBA)

4.4.3 Principal Investigators are not permitted to sign on behalf of the institution but may be requested to sign as “read and understood”.

4.4.4 Receipt of the contract, ongoing progress and final approval will be tracked in the CTO operations database.

4.4.5 Final execution of the CTA will be contingent on the notice of budget approval and payment terms from the department/division.

4.4.6 The final PDF version of the document will be maintained by the CTO. Any originals will be sent to the department/division for filing with the study documents.

4.4.7 Upon final execution of the CTA, the CTO will provide a release of indemnification to the UC IRB.

4.4.8 All CTAs will be entered in Cobblestone (UCPC, LLC contract tracking system) with an expiration date of two (2) years unless otherwise indicated in the CTA.

4.4.8.1 The system will provide notification of upcoming expirations dates to the CTO Contracts Coordinator 30 days prior to potential expiration.

4.4.8.2 The CTO Contracts Coordinator will notify the departments/divisions and determine if the expiration date needs to be extended and inquire whether an amendment is required.

4.5 Amendment

4.5.1 The CTO Contracts Coordinator is responsible for facilitating review and approval of amendments.

4.5.2 For all amendments to CTAs executed prior to July 1, 2012 language will be updated to reflect the conversion of UCPC, LLC into an Ohio nonprofit limited liability company (University of Cincinnati Physicians Company, LLC).

4.5.3 Amendments must be signed by a person with institutional signatory authority for UCPC, LLC (as defined above in 4.3.3) and (when applicable) a person with departmental/division signatory authority.

4.5.3.1 Department Chair

4.5.3.2 Executive Director, Business Administration (EDBA)

4.5.4 Principal Investigators are not permitted to sign on behalf of the institution but may be requested to sign as “read and understood”.

4.6 Budget

4.6.1 The CTO is available to serve as a resource to address specific budgeting questions, pricing on services, secondary budget review, complete budget analysis, and sponsor negotiations.

4.6.1.1 Document the requested service(s) on the CTO Cover Sheet and contact a CTO Clinical Trials Administrator for any of these services.

4.6.1.2 If you are requesting budget development and negotiation by the CTO (provided free of charge), please provide the protocol and proposed sponsor budget.

4.6.2 The CTO or legal consultant will be responsible for obtaining final budget approval from the department/division.

4.6.3 The CTO Clinical Trials Administrator will review all budgets prior to execution to ensure basic requirements are met:

4.6.3.1 Startup costs

4.6.3.2 30% overhead

4.6.3.3 IRB fees

4.6.3.4 Institutional Review fees

4.6.4 Budget considerations:

4.6.4.1 Startup costs include but are not limited to:

4.6.4.1.1 Regulatory preparation and submission

4.6.4.1.2 Source document and CRF development

4.6.4.1.3 Communication with the sponsor

4.6.4.1.4 Pharmacy (IDS) start up and closeout costs

4.6.4.1.5 Investigator meeting

4.6.4.1.6 Protocol review

4.6.4.1.7 Study specific training

4.6.4.1.8 Coordination with other departments/divisions if necessary for services

4.6.4.1.9 Facility approval if done at University Hospital

4.6.4.2 Per-participant costs include but are not limited to:

4.6.4.2.1 Principal Investigator time

4.6.4.2.2 Study Coordinator time

4.6.4.2.3 Tasks

4.6.4.2.4 Vital signs, inclusion/exclusion, etc.

4.6.4.2.5 Procedures

4.6.4.2.6 Based on flow chart

4.6.4.2.7 Laboratory tests

4.6.4.2.8 Participant compensation

4.6.4.2.9 Administrative work

4.6.4.3 Variable costs include but are not limited to:

4.6.4.3.1 AE/SAE reporting

4.6.4.3.2 Shipping

4.6.4.3.3 Supplies

4.6.4.3.4 Printing

4.6.4.3.5 Audits

4.6.4.3.6 Monitor visits

4.6.4.3.7 Sponsor interactions

4.6.4.3.8 Participant reimbursement (travel, meals, lodging, etc.)

4.6.4.3.9 Advertising

4.6.4.3.10 Study specific phone lines

4.6.4.3.11 Screen failures (pro-rated)

4.6.4.3.12 Study specific training

4.6.4.3.13 Protocol amendments

5.0 LIST OF ATTACHED FORMS

5.1 ADM-009-01-A1 CTO Cover Sheet

5.2 ADM-009-01-A2 Mutual CDA Template

5.3 ADM-009-01-A3 Amendment Template

5.4 ADM-009-01 A4 Process Flowcharts

6.0 REFERENCES

6.1 None

7.0 APPROVAL

Signature on file	21/AUG/2012
VP of UC HEALTH RESEARCH OR DESIGNEE	DATE