UConn Health
Office of Clinical & Translational Research
Standard Operating Procedures

Title: Establishing Standard Operating Procedures for the UConn Health Office of Clinical & Translational Research	
Relates to Policy/Procedure: NA	
SOP#: 100-08	Version 4.0
Prepared by: Judie Fine	Original date: 1/5/08
Approved by: Judi Kulko	Date approved: August 19, 2016

Purpose and Applicability: The purpose of this document is to establish a uniform process for the preparation, review and approval of the UConn Health Office of Clinical & Translational Research (OCTR) standard operating procedures (SOPs).

Scope: SOPs are written to describe methods, processes or procedures in sufficient detail to serve the following purposes:

1. Document established procedures
2. Provide staff with references for specific tasks
3. Help management evaluate the adequacy of procedures
4. Ensure the smooth operation of the Office
5. Provide an historical record of procedures in use at a given time

Methods: SOPs should be written by an individual experienced in the process to be described, or by interviewing an individual experienced in the process to be described. SOPs should be reviewed and approved by peer reviewers and appropriate management prior to the use of an SOP. A set format in styling, information required, and a numbering system is required, as well as at least annual review to ensure that the procedure is up-to-date, still relevant and being followed by staff. An archival system is needed to ensure that an historical record can be maintained and only current SOPs are available for staff use.

Responsibilities:

1. It is the responsibility of staff to identify the need for development or revision of an SOP and convey that need to the Executive Administrator of the Office.
2. It is the responsibility of the author of an SOP to include sufficient detail that the process or procedure can be followed by another person when needed.
3. It is the responsibility of the author to request peers to review the SOP to determine whether it contains sufficient detail.
4. It is the responsibility of the Executive Administrator to review and approve the SOP.
5. It is the responsibility of the entire staff to ensure that a procedure or process follows the details noted in the individual SOPs.

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Procedural Steps:

1. When writing SOPs, the detail used should include both procedural requirements (exact instructions) and guidance information on the procedure
2. Procedural requirements must be followed exactly, while guidance information is used to help perform the procedure.

Numbering System:

The following numbering system has been assigned to OCTR SOPs:

SOP 100 Series: Establishing Standard Operating Procedures (SOP) for the UConn Health Office of Clinical & Translational Research (OCTR)
SOP 300 Series: Negotiation and Execution of Pharmaceutical Contracts
SOP 400 Series: OCTR Website
SOP 500 Series: OCTR Shared Drive
SOP 700 Series: Reconciliation of Research Accounts
SOP 800 Series: Monitoring/Auditing of Research Billing Compliance
SOP 900 Series: Budget Workbook
SOP 1000 Series: OCTR Access Data Base Files
SOP 1100 Series: Travel
SOP 1200 Series: Billing of Participant Research Charges to Correct Payor

"Year" of SOP initial creation is captured in the hyphenated SOP # (e.g., SOP #100-08 was created in the year 2008; SOP #302-10 was created in the year 2010)

Date Revised: 8/19/16	Revised by: Diane Clavette
Reason for revision: To Reflect changes to our Policy	
Date revised version sent to archives & current revision version # advanced: 8/19/16	