UConn Health
Office of Clinical & Translational Research
Standard Operating Procedures

Title: Office of Clinical & Translational Research (OCTR) Data Base Files	
Relates to Policy/Procedure: NA	
SOP#: 1000-14	Version 3.0
Prepared by: Diane Clavette	Original date: 2/18/14
Approved by: P. Hudobenko	Date approved: 6/30/18

Purpose and Applicability: The OCTR Data Base File is a document management tool that allows staff to query data through the hard drives of each computer.
The purpose of the 1000 series of SOP is to establish a uniform process for the naming and saving of documents relating to the various areas of activity undertaken by the OCTR.

Background and Significance: Documents and data created and/or received by each staff member should be named and saved in a standardized way. Those same documents also need to be available to every other staff member.

Scope: The OCTR Data Base File should contain all documents and data relating to the Contracts and Budget Workbooks of clinical trials at the University of Connecticut Health Center that could be needed by any OCTR staff member.

Responsibilities: It is the responsibility of each OCTR staff to save documents and/or data to the appropriate Data Base File folder, and to format the name of the folder according to standard operating procedures.

Procedural Steps:
There is an individual SOP for each level of data base in the 1000 series.

A. The "first level" consists of a line for each major category of OCTR contract activities, e.g., CTA's, CDA's, Amendments, LOI's, IA's, Co-Operative Group Studies and Master Contracts.
Within this level each file has the following:
>>> ID #
>>> Received Date
>>> Initial RL Date
>>> OCTR Done Date
>>> Sent to Co Date
>>> IRB Approval Date
>>> Fully Executed Date
>>> Document Type
>>> Sponsor
>>> CRO
>>> PI Name
>>> Protocol
>>> Department

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        Status
        IRB Number
        Notes
        Fully Executed
        Pending
        LOI
        IA
        SI
        Contact
        Comments

B. The "second level" consists of a line for each budget workbook activities, e.g., Complete, Hold, Not Yet Received, Pending and Pending Other.
Within this level each file has the following:

        ID #
        PI Name
        Department
        Sponsor
        Sponsor Type
        Protocol Short Name
        Protocol Number
        Protocol Title
        Phase
        IRB Number
        IRB Status
        Banner Fund #
        InfoEd Log #
        Study Status
        BW Status
        Contract Status
        Administrator
        Notes
        Patient Enrollment:
            Patient Contracted
            Patients Enrolled
            Patient Screen Failures
        Study Specific Dates:
            Clinicaltrials.gov Number
            Prepacket Received Date

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     Prepacket Complete Date
     BW Memo Date
     BW Final Memo Date
     IRB Approval Date
     Routing Complete Date
     Banner Start Date
     Banner End Date
     Fund Closure Date
     Trial Initiation Date
     Study Closure Date
   Study Status Indicators:
     IRB Approved
     Routing Complete
     OCTR Banner Setup
     Enrolling
     Negotiated By OCTR
   Financials:
     Non-Refundable Start Up Payment
       Initial Start Up
       Negotiated Start Up
     Gross Revenue
       Initial Proposed Revenue
       Final Negotiated Revenue
     OCTR Value: Final – Initial Gross Revenue
       Value Added
     Total Operating Expenditures
       Operating Expenditures
     Net Profit / (Loss)
       Initial Net Profit/Loss
       Negotiated Profit/Loss
   Award
   Expenditures
   BW MEMO
   AMD
   Medicare Analysis
   Unobligated Balance

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Revision date: 6/30/18; 8/23/16	Revised by: D. Clavette
Reason for revision: 3.0 Use of BEAN number and Case Numbers no longer needed. 2.0 Name change and additional categories	
Date revised version sent to archives & current revision version # advanced: 6/30/18	