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 2.0
Prepared by: Diane Clavette	Original date: 2/18/14
Approved by: Judi Kulko	Date approved: 8/23/16

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

Title: Office of Clinical & Translational Research (OCTR) Data Base Files	
Relates to Policy/Procedure: NA	
SOP#: 1000-14	Version 2.0
Prepared by: Diane Clavette	Original date: 2/18/14
Approved by: Judi Kulko	Date approved: 8/23/16

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 #
BEAN
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

Title: Office of Clinical & Translational Research (OCTR) Data Base Files	
Relates to Policy/Procedure: NA	
SOP#: 1000-14	Version 2.0
Prepared by: Diane Clavette	Original date: 2/18/14
Approved by: Judi Kulko	Date approved: 8/23/16

- Prepacket Received Date
- 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

Title: Office of Clinical & Translational Research (OCTR) Data Base Files	
Relates to Policy/Procedure: NA	
SOP#: 1000-14	Version 2.0
Prepared by: Diane Clavette	Original date: 2/18/14
Approved by: Judi Kulko	Date approved: 8/23/16

C. The "third level" is within the Clinical Trails Form section consists of Case Numbers Assigned for each trial.
Within this level each file has the following:

Enrollee Number
First Name
Last Name
DOB
MRUN
Case #
BEAN #
Study IRB #
Assigned Date
Case Closed

Revision date: 8/23/16	Revised by: D. Clavette
Reason for revision: 2.0 Name change and additional categories	
Date revised version sent to archives & current revision version # advanced: 8/23/16	