UConn Health
Office of Clinical & Translational Research
Standard Operating Procedures

Title: OCTR Shared Drive – Investigators (Clinical Trials)	
Relates to Policy/Procedures: NA	
SOP#: 501-08	Version 3.04.0
Prepared by: D. Clavette	Original date: 4/10/08
Approved by: P. Hudobenko	Date approved: 6/30/18

Purpose and Applicability: To standardize configuration of folders on the OCTR Shared Drive in a folder "Investigators".

Background and Significance: Please see SOP 500-08.

Scope: This SOP covers the "Investigators" folder levels only.

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

Procedural Steps:

1. First folder level in this SOP is named "Investigators".

2. Second level, a folder is named for each Principal Investigator (PI) who has interacted with the OCTR. Only the PI's last name is to be used unless there are two PIs with the same last name, in which case the last name with a first initial should be used (e.g., Jones, J). In the case of duplicate last name and first initial, the last name with full first name should be used (e.g., Jones, John).

3. Third level folders under "Investigators" are named for the clinical trial sponsor. PIs with multiple trials will have a sponsor folder for each trial. For a PI who has multiple trials with the same sponsor, there should be a folder for each trial. In no case should documents from two different trials be mixed in a PI or in a sponsor folder. Sponsor folders should be named as follows: The name of the sponsor.

4. Fourth level (if more than one trial for the sponsor the folder is the protocol short name) folders under each sponsor in "Investigators" are named as follows, and appear in alphabetical order on the Shared Drive.
    - **Banner and Fiscal Package documents**
      This folder should contain the Memorandum from Research Administration & Finance setting up the Banner account and any documents/correspondence relating to the Fiscal Package
    - **Budget and CTA**
      This folder should contain only the sponsor's budget, any budget amendments, preliminary CTA, if applicable

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- **BW Preliminary Packet**
  This folder should contain only the Preliminary Budget Information Packet
- **BW Summary & MEMO**
  This folder should contain the OCTR completed BW summary, any trial-related BW screen prints and the OCTR memo to the PI that accompanies the workbook summary
- **Compliance**
  This folder should contain Medicare review sheet relative to the National Coverage Decision of 2000 for the clinical trial and any relevant documents
- **Correspondence**
  This folder should contain all emails and other correspondence pertaining to study **except** Banner related correspondence (see "Banner and Fiscal Package documents" folder above)
- **ICF (Informed Consent Form)**
  This folder should contain the ICF and any revised versions
- **IRB Documentation**
  This folder should contain the IRB approval of the trial and any relevant documents (e.g., revised letter of approval)
- **Miscellaneous**
  This folder should contain only documents and/or data that do not appropriately fit into other named folders

- **Payments**
  This folder should contain scans of payments made by the sponsor to the clinical trial fund
- **Protocol & Amendments**
  This folder should contain the protocol, protocol revisions and any/all amendments
- **Trial Initiation Forms**
  This folder should contain the Clinical Trials Initiation Form

- **Budget Initiation Meeting**
  This folder should contain all the information given at the Budget Initiation Meeting

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- **Budget Attestation Form Signed**
  A pdf of the signed form by the PI

- **Budget Check List Form Signed**
  A pdf of the signed form by the PI

Revision date: 6/30/18; 8/24/16; 2/28/14	Revised by: D. Clavette
Reason for revision: 4.0 Update the folders 3.0 Name change 2.0 Reflect procedure changes	
Date revised version sent to archives & current revision version # advanced: 6/30/18	