

**UConn Health**  
**Office of Clinical & Translational Research**  
**Standard Operating Procedures**

Title: Budget Initiation Meetings	
Relates to Policy: 900-11; 1400-17	
SOP#: 1401-17	Version 1.0
Prepared by: J. Kulko	Original date: 12/29/2017
Approved by: J. Kulko	Date approved: 12/29/2017

**Purpose and Applicability:**

To ensure that all research staff participating on a clinical receive education necessary to identify and manage the clinical trial charging and billing process in compliance with institutional, state, federal policies and regulations as well as the approved sponsor budget appended as part of the clinical trial contract.

**Background and Significance:**

Prior to the implementation of this series of SOP's there was no policy or procedure mandating the requirement for a formal Budget Initiation Meeting for all studies that open at UConn Health that have a Budget Workbook.

**Scope:**

Budget initiation meetings were held for all clinical trials that produced JDH and or UMG charges. This policy expands the studies to include all clinical research/ trials that have JDH and or UMG charges, pharmacy charges, and/or receive funding from an outside agency.

**Responsibilities:**

It is the responsibility of the staff in OCTR to schedule a Budget Initiation Meeting for all appropriate clinical research/trials as described in scope.

It is the responsibility of the PI to ensure that all research staff working on the study, including the PI attends the budget initiation.

It is the responsibility of OCTR staff to review all items on the Budget Initiation check list with the research staff, answer questions and make needed changes to the BWB.

**Procedural Steps:**

Staff in OCTR set up budget initiation meeting with research team after clinical trial is fully approved by the IRB, the CTA/ budget have been approved and executed by the sponsor and UConn Health and before any patients are accrued.

All documents in the Budget Initiation packet are reviewed individually (listed on the Budget Initiation check list.

PI will sign the Budget Attestation Form if it has not been previously signed.

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PI and OCTR meeting leader will sign off on the Budget Initiation Check List.

A Budget Initiation may need to happen again if a modification to the protocol causes significant budget changes.

Revision date:	Revised by:
Reason for revision:	
Date revised version sent to archives & current revision version # advanced:	