

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

Title: Budget Workbook	
Relates to Policy/Procedures: 2006-07	
SOP#: 900-11	Version 3.0
Prepared by: Judie Fine	Original date: 5/12/11
Approved by: Judi Kulko	Date approved: 8/19/16

**Purpose and Applicability:** To outline and document activities and processes that ensure that all Principal Investigators (PI) who participate in human clinical research activities, including clinical trials within UConn Health complete a Budget Workbook that is compliant with all institutional policies and procedures and federal regulations prior to study contract budget negotiations and submission of the study to the Institutional Review Board.

**Background and Significance:** The Budget Workbook was developed to standardize the research budget process at the UConn Health. It provides PIs with a tool to:

- Calculate accurate study budgets for clinical trials regardless of the sponsor;
- Provide a mechanism to assure research financial compliance
- Reduce institutional exposure relative to research billing errors
- Provide a mechanism to continually monitor the process
- Decrease the time it takes to negotiate a budget with the sponsor

The Budget Workbook allows the PI, department chair and research administration to make an informed decision regarding institutional participation in a clinical research/trial project.

**Scope:** This SOP applies to all clinical research/trial projects involving research-induced **medical and/or dental** interventions and research-related patient charges generated from medical, dental, behavioral, social science, outcomes and health services research involving human subjects conducted at the UConn Health. This procedure includes all clinical trials/clinical research that are Industry sponsored/funded, Federally sponsored/funded (including cooperative groups), foundation sponsored/ funded or institutional/department funded..

**Responsibilities:**

PI and Research Staff

- It is the responsibility of the PI, the study coordinator and other appropriate research staff to accurately complete all sections of the *OCTR Preliminary Budget Workbook Packet*, the current version of which is found on the OCTR website under the "forms" tab.
- Prospectively identify Protocol Induced Costs and Routine Clinical Services associated with the clinical trial and provide correct CPT codes
- Prospectively identify “any cost sharing” to be absorbed by the department
- Be available to answer questions regarding the proposed or if necessary meet in person

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- Review the budget workbook and memo and notify OCTR staff of any changes or corrections within 3 days of receipt
- Accept and sign off on the final budget
- Decide whether or not to proceed with opening of the clinical trial
- Provide account number to cover costs if budget is not adequate to cover costs of the clinical trial

OCTR Administrative & Clinical Research Coordinator

- It is the responsibility of the OCTR Administrative & Clinical Research Coordinator with the help of the Reimbursement Coding Specialist to Complete a “Medicare National Coverage Determination” (NCD) assessment to identify if the trial is a “qualifying clinical trial”
- Under the supervision of the OCTR Executive Administrator, complete the Budget Workbook in FileMaker Pro using information contained in the Preliminary Budget Workbook Packet, obtaining any other necessary information from appropriate sources, including querying the research staff.
- Send a first iteration of the budget workbook with a memo citing the assumptions that were used to construct the budget to the PI and study coordinator
- Document that a budget workbook is in negotiation or complete by sending an IRB memo to the study coordinator
- Complete budget negotiations with sponsor
- Send final budget workbook and memo to PI for final review and signature

Reimbursement Coding Specialist

- Work with the Administrative and Clinical Research Coordinator to produce the Medicare Coverage Analysis for the clinical trial under review and
  - Assign clinical trial charges within the clinical trial as protocol induced (PIC) and routine clinical services (RC)
  - Provide resources to document decision process for PIC and RC

IRB Administrator

- It is the responsibility of the IRB Administrator to confirm there is documentation of OCTR Budget Workbook approval (or OCTR memo waiving need for a Budget Workbook) for any proposed research that will generate research charges (e.g., blood draw, x-ray, drug administration, etc.) before research is submitted for review

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**Procedural Steps:**

The PI/research team does the following

- Sends study protocol, including schema of patient events and all proposed amendments, study budget, as proposed by sponsor
- Sends copy of most recent informed consent document (ICF)
- Makes changes to subject injury language in consent
- Lists of all Protocol Induced Charges PIC with appropriate CPT codes
- Lists of Routine Clinical Services with appropriate CPT codes
- Lists all appropriate time and effort
- Completes Preliminary Budget Workbook Packet, using the current version on the OCTR website under "Forms" tab
- Lists of staff who will cost share
- Reviews the first iteration of the budget workbook and responds to OCTR with any changes or corrections within 5 days of receipt
- Gives final approval for the budget and signs appropriate approval document
- Confirm that PI will proceed in opening the clinical trial/research
- Provides account information to charge overages if budget does not adequately cover costs of the clinical trial
- Uploads the budget workbook or Budget exemption into the IRIS system with IRB application

OCTR the Administrative & Clinical Research Coordinator:

- Completes a Medicare Coverage Analysis with input from the Reimbursement Coding Specialist of the clinical trial and completes Medicare Coverage Analysis Form
- Sets up a Budget Workbook meeting and/or phone conference is scheduled with OCTR and research staff including PI, study coordinator and department/program administrator
- Uses this information and the researchers' understanding of the protocol and assignment of all charges to prospectively develop the Budget Workbook for the individual clinical trial
- Fully negotiates budget with sponsor
- Provides a Summary of Costs for the study emailed to the PI for his/her approval approximately 1 week (7 working days) after ALL of the information needed to complete the Budget Workbook
- Makes necessary changes as directed by PI

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- Signs off on final budget and put copies in paper and electronic file

Revision date: 8/19/16; 8/20/13	Revised by: J, Kulko
Reason for revision: 3.0 Reflect changes to policy and name change of institution 2.0 Reflect additions of Dental studies and changes to medical review.	
Date revised version sent to archives & current revision version # advanced:8/19/16	