

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

Title: Clinical Trial Budget Supplementation	
Relates to Policy/Procedure: 2006-10	
SOP#: 704-09	Version 3.0
Prepared by: C. Propfe, J. Fine, B. Jones	Original date: 8/4/09 originally as 701-09
Approved by: Judi Kulko	Date approved: 10/21/2016

**Purpose and Applicability:** Study reconciliation is to be conducted by the OCTR to ensure Banner Fund activity is consistent with the Final CTA and budget as documented in the Medicare Coverage Analysis and the Budget Workbook. Revenue, patient accrual, billing charges, research staff salary and other costs are reviewed over the lifetime of the study.

To ensure that accounts that hold funds provided from external and internal sources to support clinical trials and/or clinical research are managed according to institutional policies, accounts are supplemented when the accounts have been spent down and resources (i.e. Sponsor Payments) become available.

**Background and Significance:** Please see SOP 700-09

**Scope:** Most industries apply a centralized business model to promote greater efficiency for meeting financial management requirements. The goal here is to utilize this same theory with respect to clinical trial management by:

1. Involving the OCTR in most stages of the clinical trial, from beginning to end.
2. Reconciling clinical trial budgeted revenues and expenses to actual revenues and expenses in a clear and accurate standardized approach.
3. Prevention of inappropriate or excess spending by conducting periodic review and maintaining a reasonable budget based on payments received and in some cases, payments that are imminent.

**Responsibilities:**

1. It is the responsibility of the Reimbursement Analyst to identify which clinical trials are in need of budget supplements.
2. It is the responsibility of the Reimbursement Analyst to report to the Department Administrator / Study Coordinator which clinical trials have been supplemented.
3. It is the responsibility of the Reimbursement Analyst to complete a Banner Account Initial Budget or Supplement Memorandum workbook.
4. It is the responsibility of the Executive Administrator to review and approve the budget supplement.

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**Procedural Steps:**

1. Run the "OCTR Bud\_Sup Report" found in the SQL Server Reporting Services- Research Finance Reports; identify a study in need of budget supplementation by reviewing the Revenue Activity in excess of Budget. Variances over \$1,000 should be considered for budget supplement or on an as needed basis for variances less than \$1,000.
2. Verify that this account has been reconciled initially and if not, a First Participant Billing Reconciliation should be done concurrently (refer to 701-09).
3. Perform a review of Revenue and Expenses, inception to date. Open the study account in the Banner FRIGITD screen.
  - a. Compare totals for revenue and major expense categories in the budget column versus activity to determine if variances exist. Major expense categories include:
    1. Salaries & Wages
    2. Purchased Services
    3. Supplies/ Minor equipment
    4. Indirect costs
  - b. Follow up with the Study Administrator and discuss the reasons behind significant variances and make recommendations for adjustments where appropriate.
4. Review the Initial Budget and approved budget distribution entered in Banner and apply distribution to the variance above.
5. Supplement the Budget in Banner using the appropriate FOAP, paying attention to the allocation specified in the Budget Workbook

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- a. Complete and distribute the memorandum workbook to Department Administrator and copy Research Administration, Sponsored Program Specialist in support of the monthly BOT-Report of New Awards.
- b. These procedures are also to be conducted at the final reconciliation and clinical trial close-out (SOP 702-09)

Revision date: 10/16/16; 5/7/10	Revised by: J. Kulko, B. Jones
Reason for revision: 3.0 Update process and names. 2.0 To revise SOP 701-09 version 1.0 to include only clinical trial reconciliation in version 2.0, and remove budget supplementation from that SOP to a new unique SOP.	
Date revised version sent to archives & current revision version # advanced: 5/13/10; 9/29/16	