

UConn Health
Office of Clinical & Translational Research
Standard Operating Procedures

Title: Clinical Trial Close-Out for Studies Prior to Budget Workbook	
Relates to Policy/Procedure: 2006- 10	
SOP#: 703-10	Version 2.0
Prepared by: Barbara Jones	Original date: 5/4/2010
Approved by: J. Kulko	Date approved: 11/9/2016

Purpose and Applicability:

Final study closeout and financial review is to be conducted by the OCTR Reimbursement Analyst to ensure Banner Fund activity is consistent with the CTA and budget as documented in the Medicare Coverage Analysis and the Budget Workbook. Revenue, patient accrual, billing charges, and other costs are reviewed over the lifetime of the study. Studies that are fully compliant with SOP 706-16 are eligible for financial review and close-out. However, many trials were initiated prior to the development of the Budget Workbook. This SOP addresses those trials.

Background and Significance: Please see SOP 700-09

Scope:

The procedures in this SOP relate only to those trials initiated prior to the development of the Budget Workbook.

Responsibilities:

1. It is the responsibility of the Reimbursement Analyst to notify Department Administrator / Study Coordinator of clinical trials whose end dates have been reached in the Banner.
2. It is the responsibility of the Department Administrator / Study Coordinator to identify which clinical trials are in need of close-out.
3. It is the responsibility of the Department Administrator / Study Coordinator to provide a residual account number for potential account balance to be placed at completion of trial close-out.
4. It is the responsibility of the Reimbursement Analyst to complete the Report of Expenditure (ROE) workbook, obtain necessary signatures, including PI, and execute closing journal entries in Banner.
5. It is the responsibility of the Reimbursement Analyst to verify that clinical trials are compliant with SOP 708-16; Clinical Trial Reconciliation before advancing to the financial review and close-out.

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6. It is the responsibility of the Executive Administrator to review and approve the ROE workbook.

Procedural Steps:

1. Open the study account in the Banner FRIGITD screen.
 - a. Compare subtotals and totals for revenue and major expense categories from Banner to those figures in the budget column versus activity to determine if variances exist.
 - i. Major expense categories include:
 1. Salaries & wages
 2. Purchased services
 3. Supplies/minor equipment
 4. Indirect costs
 - b. After determining the cause of the variance, provide documentation to back up the reason for the variance and present in final report. All substantial variances will be justified in writing or adjustments will be proposed to make appropriate corrections.
 - c. Compare the actual revenue transactions via the Banner FRIGITD screen and per the CTA payment schedule.
 - i. Make note if remaining funds in account (per contract) need to be refunded to sponsor, or if the funds can be transferred to P.I.'s departmental residual account.
 - d. If account balance is negative, notify Study Administrator.
 - e. Study Administrator shall provide an account number to charge the negative balance at the time of final closing.
 - f. Study account cannot be closed until negative balances have been resolved.

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4. PI Invoice or Sponsor Refund
- c. Once the Approved and Signed ROE package is received in OCTR, Reimbursement Analyst will follow the Banner Procedures for Closeout and Residual Transfer.
 - d. Upon completion of all of the above, Reimbursement Analyst will follow Banner Procedures for Final Termination of Trial Fund. Fund will be terminated on screens FTMFUND, FRMFUND, FZMACCI, and marked as I on FRAGRNT.

Revision date: 10/26/2016	Revised by: B. Jones
2.0 Reason for revision: Update procedure	
Date revised version sent to archives & current revision version # advanced: 09/29/2016	