

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

Title: Clinical Trial Close-Out	
Relates to Policy/Procedure: 2006-10	
SOP#: 702-09	Version 4.0
Prepared by: C. Propfe, J. Fine, B. Jones, J. Kulko	Original date: 7/29/09
Approved by: Judi Kulko	Date approved: 10/21/2016

**Purpose and Applicability:** Final 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 closeout.

**Background and Significance:** Please see SOP 700-09 and 706-16.

**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. Review of clinical trial budgeted revenues and expenses compared to actual revenues and expenses in a clear and accurate standardized approach.
3. Maximizing revenue capture and increasing profit by verifying sponsor payments prior to closing a clinical trial.

**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 Banner.
2. It is the responsibility of the Department Administrator / Study Coordinator to identify which clinical trials are in need of closeout.
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 closeout.
4. It is the responsibility of the Reimbursement Analyst to complete the Report of Expenditure (ROE) workbook, obtain necessary signatures, including the PI, and execute closing journal entries in Banner.

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5. It is the responsibility of the Reimbursement Analyst to verify that clinical trials are compliant with SOP 706-16 – Clinical Trial Billing Reconciliation before advancing to the final financial review and closeout.
  
6. It is the responsibility of the Executive Administrator OCTR 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.

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- 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.
  - g. Any errors that are documented need to be transferred (debited or credited) to and from the correct accounts.
  - h. A final budget adjustment will be made to the Banner fund to eliminate any difference between Revenue (Payments) received and Budgeted Revenue
    - i. All transactions need to be properly documented
2. Complete the Report of Expenditure (ROE) workbook
- a. Do not proceed unless Budgeted Revenue equals Payments received (Revenue Activity in Banner)
  - b. Open Excel workbook - clinic trial ROE template or copy an existing ROE to a new file.
  - c. Proceed to FRIGITD screen and select:
    - i. HELP
    - ii. Then EXTRACT DATA (NO KEY),this opens a spread sheet
    - iii. A new window will open in Excel. Copy data.
    - iv. Paste to the “download tab” in the ROE workbook (this populates the ROE with the inception to date budget dollars and activity)
    - v. Fill in empty cells in column B of the “Cover” TAB in the ROE workbook.

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vi. Print the following pages and mail to the Department administrator for signatures.

1. ROE
  2. Reconciliation
  3. Requisition
  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: 10/14/16; 5/29/14; 5/6/10	Revised by J. Kulko. B. Jones
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