UConn Health
Office of Clinical & Translational Research
Standard Operating Procedures

Title: Clinical Trial Early Reconciliation	
Relates to Policy/Procedure: 2006-10	
SOP#: 701-09	Version 4.0
Prepared by: J. Fine, C. Propfe, J. Kulko, B. Jones	Original date: 8/4/06
Approved by: J. Kulko	Date approved: 10/21/2016

Purpose and Applicability: Clinical Trial reconciliation is to be conducted by the OCTR Reimbursement Analyst for the purpose of:

1. Assessing accuracy of research accounts by verifying actual revenue, patient accrual, research charges and billing costs after at least 1 participant has been accrued to the clinical trial
2. Verifying the validity of the Medicare Coverage Analysis
3. Verifying the validity of the Budget Workbook
4. Verifying the validity of the Banner account

Reconciliation done early in the trial and continuing on a pre-determined basis helps to verify and improve the billing compliance challenges associated with clinical trials.

Background and Significance: Prior to the implementation of this series of SOP's, clinical trials/clinical research at UConn Health were not reconciled by utilizing a universal procedure. Reconciliation was up to the discretion of the Department Administrator. A centralized approach was deemed a necessary solution to accurately and consistently monitor the flow of cash in clinical trial /clinical research Banner funds.

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/clinical research management by:

1. Involving the OCTR Reimbursement Analyst in financial administrative oversight of clinical trials/research from the beginning to end.
2. Reconciling clinical trials/clinical research budgeted revenues and expenses to actual revenues and expenses in a clear and accurate standardized approach.

Responsibilities: It is the responsibility of the OCTR Reimbursement Analyst to:

1. Select a clinical trial /clinical research for reconciliation based on the OCTR criteria
2. Notify the Department Administrator/Study Coordinator of the scheduled reconciliation
3. To complete a "first participant reconciliation" for all trials

    a. It is the responsibility of the Department Administrator/Study Coordinator to provide all necessary information required for reconciliation to the OCTR Reimbursement Analyst upon request.
    b. It is the responsibility of the OCTR Executive Administrator to review and approve the reconciliations and report any irregularities to the Associate Dean of Research Planning and Coordination.

Title: Clinical Trial Early Reconciliation	
Relates to Policy/Procedure: 2006-10	
SOP#: 701-09	Version 4.0
Prepared by: J. Fine, C. Propfe, J. Kulko, B. Jones	Original date: 8/4/06
Approved by: J. Kulko	Date approved: 10/21/2016

Procedural Steps:

A. First Participant Billing Reconciliation
   a. Query the OCTR data log for new clinical trial/clinical research project
   b. Review participant case log
   c. Review and print out the Medicare Coverage Analysis
   d. In Filemaker Pro. Print out all pages of the BW, including Summary, Patient Calendar
   e. Print out Informed Consent from IRIS system
   f. Contact the Department Administrator and/or Study Coordinator to for relevant information including:
      i. Date clinical trial opened
      ii. List of the participants accrued including:
         1. Medical record number
         2. Dates of service for screening activities
         3. List of screen failures and dates of service if relevant

   g. Compare actual visits to those in BW to charges taken from IDX. Note the CPT codes used, the charge amount, payor (research, patient or insurance) and payment amount. Confirm the appropriate discount rate was taken for the PICs.
   h. Compare the total participant charges for UMG and /or JDH billing to the corresponding valued in the patient charges section on page 2 of the BW summary. Determine if variances exist
   i. Confirm payment from research, participant and/or insurance
   j. If billing errors found, clinical trial will be recommended for full research financial compliance audit.

B. Banner Verification
   a. Open the study account in Banner and copy the FRIGITD screen Banner into another TAB in the in the spreadsheet.
   b. Compare totals for revenue and expenses from Banner to those figures in the BW. Determine if payments and expenses charged to the fund are reasonable and accurate based on the number of subjects accrued and the clinical trial activity to date.
      i. TOTAL REVENUES in Banner should reflect up to the date contractual payments based on the clinical activity to date.

Title: Clinical Trial Early Reconciliation	
Relates to Policy/Procedure: 2006-10	
SOP#: 701-09	Version 4.0
Prepared by: J. Fine, C. Propfe, J. Kulko, B. Jones	Original date: 8/4/06
Approved by: J. Kulko	Date approved: 10/21/2016

Administrator may have to invoice for applicable research services as identified in the contract/budget.

ii. SALARES & WAGES from Banner should be reviewed for correct T&E of individual staff members assigned to the study. Effort charged to the study by pay period, as a percentage, should agree with the Patient Charges and Administrative Charges section of page 2 of the BW summary.

iii. PURCHASED SERVICES in Banner should reflect the PI's cost (after research discount is applied) of participant charges paid to JDH and/or UMG based on the clinical activity to date. Other expenses such as pharmacy, stipends, sub-contractors and any other purchased services provided for in the BW should be charged appropriately according to the BW and any agreements with parties internal or external to the institution.

iv. SUPPLIE/MINOR EQUIPMENT in Banner should reflect reasonable spending volume for supplies based on number of participants accrued to date. Spending for supplies must be limited to those documented in the final BW.

v. INDIRECT COSTS in Banner should reflect the rate loaded in Banner and as documented in the BW. Re-compute the total indirect costs and investigate any discrepancy in the banner activity.

c. Print the detail of Account 52501, Sponsor payments

d. Compare the actual revenue transactions on FRIGITD account 52501 to the Sponsor payments loaded into the BW for actual patients accrued and cycles completed.

e. If applicable, verify that start-up funds have been deposited to the corresponding Banner account

f. Review the budget section of the CTA and compare to detail remittance, when provided, to ensure proper reimbursement. Detail remittance and check copies are scanned into the Research Finance & Administration on (\\NSO-Grants) (O ;) by batch# and date.

g. Examine revenue and expenditure transactions using FRIGITD details and determine if any of the following errors were committed to revenues and/or expenditures:

i. Inappropriate or excessive spending (Over budget and in excess of planned resources)

Title: Clinical Trial Early Reconciliation	
Relates to Policy/Procedure: 2006-10	
SOP#: 701-09	Version 4.0
Prepared by: J. Fine, C. Propfe, J. Kulko, B. Jones	Original date: 8/4/06
Approved by: J. Kulko	Date approved: 10/21/2016

ii. IRB payments deposited into the study Banner account in error rather than the IRB account
iii. Incorrect F&A amount taken
iv. Non- payment or non-timely payment of participant stipends
v. Fringe benefits assessed to the clinical trial at an incorrect rate compared to BW
vi. Any additional budget discrepancies than those listed above.

h. If errors exist, work with study administrator to make corrections
i. If errors persist, notify Executive Administrator in OCTR by report.
j. Executive Administrator will notify the Associate Dean of Clinical Research Planning and Coordination
k. Executive Administrator will schedule full research financial compliance audit within 30 days

Revision date: 10/12/16; 1/20/13; 6/3/10	Revised by: J. Kulko, B. Jones
Reason for revision: 4.0 To revise the procedures based on changes to process 3.0 To update process to current method of review 2.0 To revise procedures	
Date revised version sent to archives & current revision version # advanced: 10/12/16	