Guideline Document for Clinical Research Closeouts - Non-Federal Projects

High-Level Process Steps

Detailed Breakout for Financial Closeout

Ensure All Revenue is Received

1. Gather the following documentation:
   - Sponsor Budget
     - Including any versions that have been in place
     - Generally an excel worksheet
   - Contract/Agreement
     - Note payment terms section
   - List of subjects and their visit dates
     - Including screen failures, unscheduled visits & AE visits
     - Note when each subject had each milestone visit
   - Copy of Each check/payment from Sponsor
     - Ensure payments reference what milestones the payments are for
   - Copies of all invoices sent to sponsor
   - List of IRB Submissions and Dates
     - Including amendments, renewals, etc
   - SAP report – ITD and Line Items for duration of Project

2. Validate the amount of Earned Revenue
   - During the life of the project, some type of tracking mechanism should have been maintained to track the amount of earned revenue
   - Example: A matrix of each subject visit that multiplies out the payment per visit to determine amount earned for subject visits
   - This tracking mechanism should have done the following:
     - Calculate earned revenue for any screen failures, early terms or lost to follow-ups
     - Reference contract payment terms for amounts due for these situations
     - Calculate earned revenue for any out of scopes or invoiceable subject activity
     - Unscheduled Visits
     - Invoiceable procedures – such as a liver biopsy or MRI
     - Reference contract payment terms for amounts due for these situations
     - Determine amounts earned for non-subject activity
     - IRB Submission, renewals, amendments, sae reporting
     - Startup Costs, CRU Fees, etc
     - Pharmacy Fees, document fees, etc
     - Reference contract payment terms for amounts due for these situations
     - Tally total amount of Revenue Earned
   - Validate that all anticipated and unanticipated events have been accounted for through this tracking mechanism

3. Analyze the Sponsor Payments
   - During the life of the project, some type of tracking mechanism should have been maintained to ensure that the sponsor payments were coming in to appropriately according to the contract payment terms
   - Validate that:
     - Each check was deposited correctly into SAP
       - See if any checks are missing in SAP (you would have a check but see no deposit)
       - See if any copies of checks are missing (you would see a deposit in SAP)
     - Compare sponsor payment to your earned calculation for the following:
       - Subject visit activity
       - for screen failures, early terms or lost to follow-ups
       - out of scopes or invoiceable activity
       - non-subject activity
     - Ensure all outstanding sponsor invoices have been collected
   - Determine any amount earned that has not been collected

4. Contact Sponsor to understand the variance
   - Invoice sponsor for balance as appropriate
Ensure that all Expenses are Accurate and Accounted For

1. Gather the following documentation:
   - Internal Cost Assessment (aka internal budget)
   - List of subjects and their visit dates
     - Including screen failures, unscheduled visits & AE visits
     - Note when each subject had each milestone visit
   - List of IRB Submissions and Dates
     - Including amendments, renewals, etc
   - SAP report – ITD and Line Items for duration of Project

2. Review actual expenses that hit this project fund code
   - Effort
     - Compare to internal cost assessment projections/estimation
     - PI & study staff
   - Patient Care Expenses
     - Should have already been validated during the grant billing reports charge review process
   - Other Expenses
     - Compare actuals to budget (from internal cost assessment)
     - Ensure appropriate CRU fees have been applied or transferred
   - Identify expenses that are missing
     - Work to get these expenses on the code
   - Identify recurring expenses that will need to be stopped or redirected

Ensure iForms and Standing PO’s and the like are redirected or closed

1. Work with procurement services to adjust any PO as appropriate
   - Transaction CJ15 in Sap is a good way to see the balance on any PO’s on a fund code
     - Work to get these expenses off the code
2. Work with the appropriate Unit manager to run the necessary payroll reports to identify those being paid from this fund code
   - Redirect effort assignments as appropriate

Complete closeout Checklist (attestation)/Forms/Submit for Approval

1. Form can be found on the DOCR Website:
   http://DOCR.som.duke.edu/wysiwyg/downloads/study_closeout_checklist.xls
2. Complete the form as indicated
3. Submit to CRU for signatures per CRU requirements

Non-Federal: Transfer funds for residual or overdraft

1. Once the closeout checklist is approved and signed per CRU requirements, enter the JV to bring the fund balance to zero
   - Verify fund balance
   - Enter Document per SOP for correct coding of Closeout Transfers
   - Enter document number on the completed checklist
2. Ensure document clears
   - Look for Zero Balance

Request Fund Code Deactivation

3. Send pdf copy of the completed closeout checklist via email to OSP and request the closure (deactivation) of the Fund Code (sponsoredprograms@duke.edu) indicating Clinical Research Fund Code Closure Request in the subject line.

Record Retention
1. Original signed document should be kept in CRU
2. Storage requirements should align with University Record Retention Policies