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Closeouts-All Good Things Must Come to an End

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Introduction

- **Jason Claes**

- 25 Years Experience Research Administration
- Department to Central and everything in-between
- Financial and Operations responsibilities
- Clinical Trial Management lifecycle

- **Dominic Esposito**

- 25 Years Experience Research Administration
- Central Pre- and Post-Award
- Institute/Departmental lifecycle
- Direct involvement on a Federal grant
- Single person office

- **Amanda Seymour**

- 16 Years Experience Research Administration
- Departmental lifecycle
- Central Post (financial)
- Some central lifecycle

Objectives

- Understand what you can do throughout the life of the project to help avoid the dreaded big cleanup after the end date of your sponsored project.
- Learn some tips and tricks of a closure process that you can tailor to your situation for each sponsored project.

Agenda

- Overview of Grant Management Landscape
- Identifying Common Issues
- When to start closeouts
- Closeout Checklists
- Potential Solutions
- Current situation



Overview of Grant Management Landscape and Closeouts



- High turnover, short staffed
 - Effort is shifted to putting out day-to-day fires, keeping head above water
 - Effort is shifted to training/onboarding
- Increasing Regulations
 - Creates extra steps for closeouts
- Delayed timelines
 - Grantor and Grantee actions
 - Delays start of closeouts

What Are the Implications of "Chaos at Closeout"?

- Non-compliance (e.g., effort reporting, human subjects)
- Audits
- Loss of funds to the institution (responsible for unallowable costs)
- Damaged internal relationships
- Damaged external relationships
- Lack of confidence from the sponsors
- Suspension/Debarment

Identifying Common Closeout Issues

- Portfolio management...expectations vs reality
 - Multiple funding streams: Federal, local, private, institutional, etc.
 - Personnel: Single person working on multiple projects
 - For projects similar in scope, are the other than personnel expenses on the correct funding stream?
 - Were honest mistakes made, and if so, who made them and is there time to correct them?
 - Reconciling the portfolio management system with the grant accounting system, needs to be done monthly
 - Turnover in management position

Identifying Common Closeout Issues

- No Cost Extensions

- How many have been done? Is another one allowed? Does the PI understand the limitations?

- Personnel

- Were individuals paid as contractors that should have been paid as employees?
- Were people paid as contractors or employees where there should have been a subcontract with another institution?
- Does the institutional payroll system communicate effectively with the grant accounting system?

Identifying Common Closeout Issues

- Other Than Personnel
 - Allowability, allocability, and reasonableness of costs
 - Excessive, last-minute spending especially on equipment at the end of the project
 - Significant amount of cost transfers
- Subawards
 - Have the sub-awardees been spending their funds and, if so, are they in compliance?
- Who is responsible for drawdowns at your institution and are they being done regularly?



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Identifying Common Closeout Issues – Clinical Trials

- Participant Data
 - Participant data have been captured and source documentation is available and verified.
- Case managements for participants.
 - Data records missing or still open.
 - Data devices not cleaned regarding PHI from participants.
 - Hospital vs. Sponsor bills are not reconciled.



Poll – When Does Closeout Start?

- When the award ends
- 6 Months prior to the end
- At the time of award
- 1 month prior to the end
- None of the above

Closeout Starts at the Time of Award

- Early identification of potential issues allows you to create a clear roadmap for efficient closeout management



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Closeout Starts at the Time of Award

- Post award success begins with good pre-award practices
- Key Questions to Consider
 - Was the proposal submitted close to the deadline?
 - Does your institution have a post-submission pre-award review process?
- Reading the fine print minimizes frustration and confusion
 - Make detailed notes at award setup to be referenced at closeout



Closeout Starts at the Time of Award

- Modular Budgets at submission
 - Does your institution keep a detailed budget on file?
- Startup delays can lead to time constraints, which may cause spending to occur later in the project and impact the closeout process
 - ****Set up advance account****



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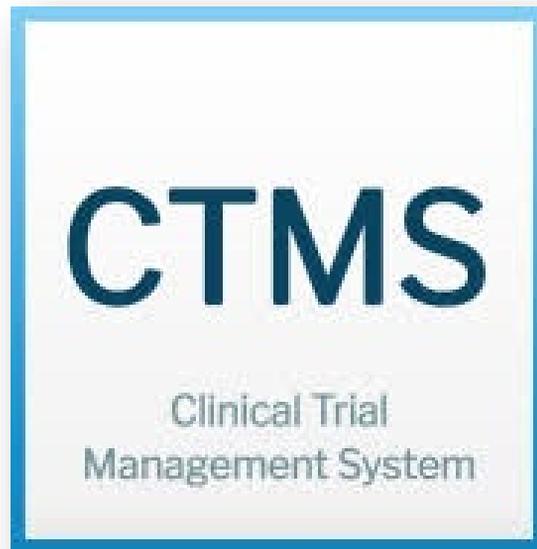
Budget Items to Review - Grants



- Personnel
- Fringe Benefits
- Equipment
- Travel
- Participant Support Costs
- Consultant Services
- Subawards

Starting Closeout at the Time of Award

- Does your institution for Clinical Trials have a good CTMS(Clinical Trials Management System) to help track participant activity that can be billed to the sponsor?
- Setting up your EMR system initially with Dot.phrases can save you a lot of headache down the road.



Budget Items to Review – Clinical Trials

- Schedule of Events
 - Startup costs
 - Patient Revenue
 - Timely billing
 - Correct fee usage for budget/billing
 - Closeout statement



The Closeout Checklist

- “Taylor” for your institution
 - Payroll
 - Payroll reports
 - Processed/pending timecards
 - Accurate payments
 - Correct classifications and fringe rates
 - Institutional recoveries for time and effort
 - Etc.



The Closeout Checklist

- Accounts Payable
 - Allowable, allocable and reasonable costs
 - Accurate expenditures
 - Requests are processed
 - Possible refunds are credited to the award
 - Etc.

- Purchasing
 - Allowable, allocable and reasonable costs
 - Purchase orders with remaining balances: Are there pending items, or can they be closed?
 - Have all invoices been submitted?
 - Etc.

The Closeout Checklist

- Compliance
 - Is there human subjects research associated with the project?
 - Have any changes to the protocol been submitted and approved?
 - Are there any Institutional Review Board (IRB) compliance issues that required reporting, and have they been reported?
 - Are there any issues related to Animal Research, Biosafety, Export Controls, etc.?
- Project income
 - Has it been identified?
 - Is it allowable under Uniform Guidance?
 - Is there proper documentation?
 - Is there a requirement to return excess income to the sponsor?



The Closeout Checklist

- Subawards
 - Is there an unobligated balance?
 - Have all the previous considerations been addressed by the sub-awardee (payroll, accounts payable, purchasing, etc.)?
 - Etc.
- Cost Sharing
 - Are costs allowable, allocable, and reasonable?
 - Is there an Indirect cost differential that is allowed by the sponsor?
 - Is there proper documentation?
 - Have all the requirements been met?
 - Etc.
- Patents and inventions
- Etc.

The Closeout Checklist

- Database
 - Database lock
 - Data storage arranged, retrieval and backup recorded
- Investigational product or study drug and pharmacy
 - Site/Local/home investigational product or study drug accounted for
 - Accountability logs and forms reviewed and filed
 - Shipping logs documentation is reviewed and filed
 - Any discrepancy documented, investigated, and resolved
 - Pharmacy documentation is in order
 - Remaining investigational product or study drug, materials, and compounds are returned or destroyed as outlined in the protocol or agreement with the sponsor

Possible Solutions

- Develop a standardized process
 - Establish internal deadlines
 - Establish clear roles and responsibilities
 - Create a checklist
 - Create an electronic repository for documentation
 - Train Project Staff and Research Administrators on Governmental, Sponsor and Institutional Requirements
 - Communicate Across the Institution and Implement a Feedback Mechanism Inclusive of Key Stakeholders
 - Utilize All Available Workflow Systems at the Institution
 - Create a Post-Closeout Debrief Process
 - Leadership Support at the Institution is Crucial



Possible Solutions

- Examples:
 - Hold project meetings 6 months, 3 months, and 1 month prior to the project end to check on the "burn rate," personnel expenses, non-personnel expenses, subaward monitoring, etc.
 - Create a deadline grid related to various fiscal year-end dates, highlighting key dates for budget modifications, new hires, payroll submissions, procurement processes, and the closure of outstanding purchase orders. This ensures that all critical tasks are completed in a timely manner.

Possible Solutions - Clinical Trials

- All unanticipated problems, adverse events, and serious adverse events have been documented, resolved, and reported as required
- All study documentation available and securely retained
- eConsents or ICFs on file
- Study files reconciled with a CTMS or a Trial Master File system
- Study closure forms submitted to IRB/EC

Possible Solutions - Clinical Trials

- IRB/EC closure confirmed
- Any discrepancy documented, investigated, and resolved
- Final inventory/reconciliation of remaining or unused trial supplies, including devices loaned to participant and equipment loaned to the local site, completed
- Trial supplies returned to the sponsor or destroyed, as applicable
- Biospecimens recorded, stored for future use (where permitted), and documented

Poll

- What does your closeout backlog look like?
 - We are current (as much as we can be)!
 - Less than 100
 - 100-300
 - 300-500
 - 500-1,000
 - More than 1,000



Real World Example-Ongoing

- 276 Outstanding Closeouts
 - As of October 1, 2024
 - Master list created each month with outstanding closeouts and split between each staff position, including the director
 - 2-3 added each month for each person
 - Idea is once caught up, 2-3 per person/month is manageable
 - Requires Director assistance
 - Requires Manager assistance
 - All-Hands on Deck
 - Are you able to shift FTE, part-time help?
 - The longer you let closeouts go, it becomes overwhelming

Summary

- Start at the beginning of award!
 - Making great, detailed notes (think succession planning) will help!
- Perform periodic checks
 - At invoicing, draws, reporting periods, etc...
 - Dept/Shared Services should be reconciling Monthly
- Resolve issues early on
- Perform closeout as soon as able
- Make closeouts a part of the day-to-day operations

Thank you!

- Any questions?
- We hope you have a great Tuesday!