Clinical Trials

Financial Management

Panelists

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  Financial Management Analyst for Clinical Research
  School of Medicine Office of Finance

• Pamela Gorham
  Financial Management Analyst III
  Dept. of Surgery Central Administration Office

• Christeen Butler
  Finance Practice Manager
  Dept. of Pediatrics Site Based Research Unit
Cathy O’Neill
Financial Management Analyst
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Financial Management of Clinical Research Projects

• Why is it Important?
  – Maintain the Duke “Brand”
  – Collection of Revenue
  – Appropriate assignment of Expense
  – Practices to support the Research Mission

• Where to begin?
  – Scope of Work
  – Identification of Fund Codes
Financial Reporting

- Reports available in SAP and Business Warehouse (BW)
- SBR Reports run monthly and shared with Department & SBR Leadership as well as SOM Senior Leadership
- Operational Management Tool
  - Monitor portfolio performance at the Department, Division, or PI Level
  - Make strategic decisions
  - Manage Residuals and Overdrafts
- Senior Leadership
  - Monitor performance
  - Understand Scope & Breadth of Clinical Research

Revenue Management Initiative

- Systematic process to recognize Earned Revenue for Industry Sponsored Clinical Research Projects
  - Excel tool called “Trial Tracker” in use by many SBR’s
  - Ties study visit activity and contract payment schedule
- Transition from Cash Basis to Accrual Based Accounting
  - Entries today as Topsides into BW; will be JV entries into SAP
- Collaboration between Research Team and Finance/Admin Team
Management of Expenses

• Identification of the Cost of Research
  – Infrastructure (Hub) Accounts
  – Departmentally Funded (453) Codes, often PI Initiated projects

• Consistent approach to allocation of salary cost to the studies (codes) where effort is expended

Pamela Gorham
Financial Management Analyst III
Dept. of Surgery Central Administration Office
Site-Based Research (SBR) Charter

- Scope of Research
- Key Personnel
- Clusters & Cluster Leadership
- Faculty Advisory Board
- Governance & Financial Plan
- Stakeholders
- Communication Plan

Governance

SBR reports to the Chairman of Surgery through the SBR Medical Director and departmental administrative structure
Administrative Fees

• Based on Tiers (type of study)
• Fees are due upon submission of the clinical research project to the SBR when the fund code is assigned
• A percent of the aggregate residual at the close-out of the study is transferred to the Surgery SBR

Managing Funds

• Budget development – Cover all costs associated with the clinical trials
• Billing grids
• Grant Billing Reports (GBRs)
• Invoicing
• Accounts Receivable (AR) Tracking Tools
• Reconciling Financial Statements
QUOTE

“Surround yourself with the best people you can find, delegate with authority, and don’t interfere”

Ronald Reagan

Christeen Butler
Finance Practice Manager
Dept. of Pediatrics Site Based Research Unit
Best Practices

• Understand contract and payment terms
• Understand dept SBR structure and fees that may be assessed (and when).
• Have a study startup “kickoff” meeting to determine who should do what
  – Study Team (PI, CRC, financial team)
    • Who reviews charges?
    • Who reconciles expense/revenue?
    • Who invoices?
    • Who updates tracking tools?
    • How often do we review/change effort on study?
• Communicate
  – Everyone has a specific focus, but information from your colleagues has a big impact on keeping track of study-related specifics
  – Understand that because of that diversity and focus, we don’t always speak the same “language” or use the same vocabulary – don’t be afraid to ask if you don’t understand terminology in conversation

Best Practices

• Know what you can get from the various systems in place
  – eIRB
    • Approval/expiration date
    • Amendments
    • Continuing Reviews
    • Safety events
  – eResearch
    • Enrollment
    • Consent/study activity/end billing dates
  – SAP
    • Revenue/Expense activity
    • Balance
  – SPS
    • Institutional approvals (study, indirect rates, etc)
    • Institution notes re: contract process
    • Budgeted effort
Feasibility

– For new clinical research related studies Peds SBRU requires:
  • Feasibility form
  • Protocol
  • Internal budgets (PRMO pricing for labs and procedures, IDS, DCRU, Radiology, Eye Center, etc.)
  • Time estimates for certain study related activities
  • Billing grid
  • Proposed budget (from sponsor, PI, etc)

NOTE: funding source determines which items are required for review

– SBRU leadership reviews and determines whether or not to proceed with protocol submission to IRB and/or contract negotiation, may suggest potential revisions to improve chances of success.

Internal Cost Summary

• BtB presentation by dept FPMs on CRSO website:

  http://crso.som.duke.edu/modules/crso_resrch/index.php?id=17

  Presenters:
  Christeen Butler, FPM Pediatrics
  Robert Gray, FPM Eye Center
  Virginia King-Barker, FPM Dermatology
Dept. of Pediatrics Revenue Tracking

- Designed to be flexible enough to accommodate all types of studies
- Includes budget and payment terms, tracks payments in 3 basic “statuses”
  - To Be Billed
  - Awaiting Payment
  - Payment Received
- Allows you to generate and track invoices
- Ensures that a study is not closed until all revenue earned has been received, and provides specific information when communicating with sponsors

Tracking Tool

- Components taken from FE contract
  - Payment Terms
  - Contract Budget
  - Assumptions
    - PI Info
    - Start/End date
    - Fund code
    - SPS number
    - Sponsor contact/remittance info
    - Division finance contact
Tracking Tool (cont’d)

- Billing Information
  - Invoiceables/Milestones
  - Visit payments
  - Visit specific Invoiceables

- Enrollment Log
  - Can be used for end of study patient validation submitted to CRSO
  - Drives information supplied to other sheets in the workbook
Tracking Tool (cont’d)

- Visit, Invoiceables, and Phone Logs all function in the same way:
  - Dates entered
  - Amounts populated
  - Update status as visits occur and checks are received
  - Calculates totals based on status of payment

Tracking Tool (cont’d)

- Summary Pages – populated from log sheets:
  - Revenue Status
  - Invoice Status
- Provided to SOM Finance to book accrued/earned revenue in SAP
**Tracking Tool (cont’d)**

- Generate an Invoice
- Print to PDF or paper
- Paste onto new tabs to maintain complete file/workbook

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**Clinical Research Acronyms**

- CDA – Confidential Disclosure Agreement
- CPOE – Computer Physician Order Entry: Inpatient
- CRF – Case Report Form
- CRSO – Clinical Research Support Office
- CTA – Clinical Trial Agreement
- CTBO - Clinical Trials Billing Office
- CTOV – Clinical Trials Order Verification
- DCRU – Duke Clinical Research Unit
- DPAF – Duke Project Approval Form
- IDS – Investigational Drug Services
- IDX – DUHS Appointment Scheduling System and Physician Billing System – Outpatient
- IRB – Institutional Review Board
- OCRC – Office of Corporate Research and Collaboration
- ORA – Office of Research Administration (SOM pre-award)
- ORS – Office of Research Support (Campus pre- and post-award)
- OSP – Office of Sponsored Programs (SOM post-award)
- PCA – Pending Central Approval
- PRMO – Patient Revenue Management Organization
- SBRU – Site Based Research Unit
- SPS – Sponsored Projects System
- WBS – Work Breakdown Structure (a.k.a. fund code)