CCTS Lunch and Learn

May 16, 2017
Agenda

Compliance – Brian Bates
IRB – Leslie Cooper
CTAO – Mark Marchant
OnCore – Lisa Williams
OSP – Richard McGruire
ClinicalTrials.gov – Denise McKenzie
General information and Education – Penny Jester
UAB and UAB Medicine Clinical Trials Billing:

A Team Effort

CCTS Lunch & Learn
Margaret Cameron Spain Auditorium
May 16, 2017
UAB CLINICAL TRIALS
RISK AND OPPORTUNITY PROFILE

- Customer-centered operational culture
- Pursue clinical trials with strategic focus
- Market competitiveness
- Faculty recruitment and retention

Meet Strategic Objectives

- Patient/subject safety
- Data quality
- HIPAA/research data security

Maintain Adequate Resources

- Strategic, financial, & risk alignment
- Clinical trials infrastructure
- Technology integration
- Effective/efficient processes and training

Protect Individuals, Property, & Information

Nurture a Culture of Integrity & Accountability

- Clinical trials billing
- Scientific integrity
- Conflict of interest
- FDA and other regulations
- CT.gov

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Mission Impossible?... I Don’t Think So

- Increase the support for clinical trials
- Improve the Time-To-Activation
- Ensure appropriate internal controls and standards are in place
- Improve cost recovery and budgeting processes
- Educate and train key stakeholders
- Enhance clinical research billing processes
The Bad…

- Compliance Risks
  - Clinical trial billing errors continue to emerge at established, well-respected sites—and the penalties and publicity can hit hard
  - Not having a consistent clinical trials billing process or operational safeguards can lead to:
    - Billing for services that are already paid by the sponsor (double billing)
    - Billing for services promised free in the informed consent
    - Billing for services that are for research-only purposes
    - Billing for services that are part of a non-qualifying clinical trial and do not qualify for coverage
Lost Opportunities

- Inaccurate budgeting could cost the institution money it rightfully deserves
- Lost revenue both on the payer side and in research
- Slow, delayed “time-to-activation” of a clinical trial could lead sponsors away from UAB
- Inefficient use of Human Resources
The Ugly…

- Consequences of Inappropriate Clinical Trials Billing
  - Potential loss of federal grant funding
  - Potential loss of participation in government healthcare programs (ex., Medicare; Medicaid)
  - Enforcement actions
  - Corporate Integrity Agreements
  - Loss of community trust and reputation
  - Fines and penalties
The Ugly…

- Publicly released research-related settlements
  - Emory (2013): $1.5 million
  - Tenet USC (2010): $1.9 million
  - Yale University (2006): $7.6 million
  - UConn (2006): $2.5 million
  - Cornell (2006): $4.4 million
  - Rush (2005): $1 million
  - UAB (2005): $3.39 million
Boston University - 2014

Why is Change Necessary?

The National landscape consists of tighter regulations and increased scrutiny of research costs. Noncompliance with federal regulations can lead to stringent corrective action plans and financial implications. A few examples:

University of Alabama at Birmingham (2005) $3.4M
- Unlawfully billed Medicare for clinical research trials that were also billed to the sponsor of research grants (double billing).

University of Maryland

OIG/DOJ Settlements and Fines

- University of Alabama at Birmingham - $3.35 million settlement April 2005
  - Falsely billed Medicare for researcher’s time spent on patient care when no patients had been seen & clinical research trials that were also billed to the sponsor of the grants
The Good…

- **A Team Effort to Get it Right**
  - Principal Investigator
  - Clinical Research Coordinator
  - CTAO
  - IRB
  - Department and University Administration
  - Information Technology/HSIS
  - Health Information Management
  - Patient Access/Registration/Scheduling
  - Business Office (PFS/MSO)
  - Compliance
  - …. and others!
The 3 C’s of Clinical Trials Billing

- **Coordination** of study information across multiple study documents
- **Communication** of relevant study information to the billing process
- **Cooperation** among departments and offices that may not usually work together
Longstanding and Current Challenges

- Decentralized Approach to Clinical Research Study Management
- Variability and Customized Processes
- IT infrastructure for management of clinical trials fragmented and insufficient
- Clinical Trials Research Billing is a cumbersome and highly manual process
Current Opportunities

- Decentralized Approach to Clinical Research Study Management
  - Creation of Clinical Trials Administrative Office (CTAO)
  - CTAO partnership with OSP/CIRB/OIRB/OIE/CCTS/CRSP/Compliance/Departments/Business Office (PFS/MSO)

- Variability and Customized Processes
  - Budgeting Standards
  - Standard Contractual Language (Subject Medical Injury; Co-Pays)
Current Opportunities

- IT infrastructure for management of clinical trials fragmented and insufficient
  - Enterprise-wide implementation of OnCore and PowerTrials

- Clinical Trials Research Billing is a cumbersome and highly manual process
  - Use our people, processes, and technology to create improved front-end and back-end processes that synchronize study information and guide which services are billable to payer/patient and which are billable to the study.
Questions/Discussion
Institutional Review Board:

Brief update

Leslie Cooper, CIP
IRB Director
UAB Institutional Review Board
Brief update

- Issues to be addressed within the next months:
  - Single IRB implementation (effective September 2017)
  - Changes to the Common Rule (effective January 2018)

- Within the next week, a Consent Form Boilerplate Language document will be posted on the IRB website. This will include only the required language from the Sample Consent Form. There is an English and Spanish version.
Upcoming Initiatives: CTAO

Mark Marchant, MPH, MBA, CCRP
Director, CTAO
• Electronic Subject Payment System
• Utilizes ClinCards
• Replaces Checks, Visa Debit Cards, Petty Cash
• Web Portal for Subject Entry and Visit Keeping
• Cards have no value until study visits kept in system
• Currently beta testing at 2 sites
Internal Cost Analysis

• Initiative from President’s Risk Cabinet
• Financial accountability for industry trials
• Attestation line to be added to Extramural Checklist
• Provide GL Account with submission for potential deficit
• Excel-based tool under development and testing
OnCore Enterprise Update

Lisa Williams
OnCore Enterprise Administrator
What’s Been Happening?

- Vendor Implementation Engagement
- SiteMinder Data Migration
- Working Group Creation
- System Upgrades
- Anticipated Timeline
- Training Plans
- Future Communications
Implementation Planning

- 3 month engagement between Forte (vendor) and UAB
- Assessed organizational priorities
- Provide guidance on scope, timeline, and resources
- Outline plan for technical infrastructure and system upgrades
Data Migration/Updating SiteMinder

• Main Focus - Any trials currently managed by SiteMinder
  • Existing trials with AND without clinical billables
  • Existing trials that will complete study visits 6 months from go live will not migrate

• Review of SiteMinder data completed by mid June (estimate)

• Request research unit participation
  • Update SiteMinder data
  • Validate/confirm accuracy of data once migrated
Working Groups

• Members selected from various departments and administrative entities

• Purpose is to assist with Reference Codes (drop list options) and document processes (workflows, define field usage)
  • Subject Management
  • Financial
  • Budgeting
  • Reporting/Administration
Technical System Upgrades

- Review of hardware, software, network configurations
- Upgrade database hardware and operating systems
- Upgrade of the software that enables your desktop browser to communicate with OnCore.
Anticipated Timeline
Selection of Participating Groups is Under Review

• OnCore expansion completed in Three Waves

  Wave 1
  November 2017

  Wave 2
  April 2018

  Wave 3
  September 2018

• Taking a phased roll out approach due to large number of trials and number of people to be trained

• Building project staff to accommodate implementation work load demands
Plans for Training

- For Super Users
  - Identified by Department or Division
  - Expected to be able to dedicate part of their daily schedule to providing system support to their co-workers and/or others in their department/division
  - Broader system expertise provided to this support group
  - Training expected to occur for Wave 1 in late June or early July
Plans for Training

• For Research Staff and Research Support
  • Ideally within 4-5 weeks prior to go live
  • Broken down by role
  • Estimate 2 or 3 hour sessions per role training
  • Sessions will cover
    • Protocol Management
    • Calendars (similar to SiteMinder study build)
    • Subject Management
    • Financials (Budgets)
Begin
Training

Train the trainer

Education planning

Identify super users

Train Wave 1 super users and key educators

Begin Training

Continue training

Develop materials

Go Live Wave 1

From Penny Jester; Exec Committee Update; May 2017
Communication Plans

• Monthly email updates
• Highlighted at Research Presentations
• Development of the CTAO website
• Department and Division meetings
• CCTS Lunch and Learn
• Faculty-specific awareness campaign
Next Steps

• OnCore team will communicate with department leadership when wave selection is completed
• SiteMinder contacts will receive requests for updated SiteMinder information
• Department/Division leadership will be asked for names and roles of research staff and others for training purposes.
• Work groups begin meeting
Thank You

from the OnCore Enterprise Team

OnCore@uabmc.edu
Office of Sponsored Programs:
Determining if your industry sponsored project meets UAB’s definition of a clinical trial for F&A purposes.

Richard McGuire
Grants and Contracts Officer
Office of Sponsored Programs
Differing Definitions of a Clinical Trial

• What is defined as a clinical trial scientifically is not necessarily a clinical trial for F&A purposes.
• UAB has a separate definition of a clinical trial for F&A purposes only.
• The UAB definition for F&A rate is narrower than other definitions.
Non-determinative factors for clinical trial F&A rate

- The study is listed on clinicaltrials.gov
- The protocol title says it is a clinical trial
- The study meets the FDA or other definitions of a clinical trial
- The sponsor has labeled it as a clinical trial
- You really need the 30% to make the budget work
What is UAB’s definition of a clinical trial for F&A rate purposes?

• Investigational new drug, device, treatment or diagnostic
  • Clinical testing of the new drug, device treatment, or diagnostic.
  • Human subjects only
  • According to a protocol
  • With a purpose to assess the safety, efficacy, costs, adverse reactions or outcomes
What is UAB’s definition of a clinical trial for F&A rate purposes?

• Approved drug, device, treatment or diagnostic
  • The study must be comparative in nature
    • i.e. comparing two approved drugs to determine which one is safer
  • Human subjects only
  • According to a protocol
  • To assess safety, efficacy, costs, adverse reactions or outcomes
Exclusions from the clinical trial F&A rate

- Laboratory Research
- Retrospective chart reviews, registry studies and observational studies
- Analysis of existing data or medical records
- Animal studies
- Services only
  - We may be participating in a clinical trial but only providing a service to the sponsor.
- Financial audit provisions in the contract
Tools to help you

- The OSP website
  - www.uab.edu/osp
- Your assigned grants and contracts officer or specialist.
- The F&A Clinical Trials Rate Flowchart
Industry

Overview

The Industry team within OSP is responsible for the administration of UAB research related activities which are made possible by funding received from for-profit sources. The Industry team reviews proposals for funding, reviews and negotiates contracts for execution and assists with coordination of internal and external requirements to initiate sponsored programs for UAB.

OSP is organized into three teams. Each team operates under the direction of an Associate Director. The Industry team is headed by Associate Director of Industry area who reports to the AVP of Sponsored Programs, who in turn reports to the VP of Research.

Facilities and Administrative (F&A) Costs
Clinical Trial F&A
Required Documents
UAB Extramural Checklist Instructions & Form
UAB Expedited Checklist Form
Responsible Personnel List Instructions & Form
Scope of Work Template

Additional Content Under This Topic

Clinical Trials
Contains relevant information for initiating and maintaining Clinical Trials with OSP’s guidance.

Project Master Agreements (PMA)
Summarizes Project Master Agreements.

Confidentiality Agreements (CDA)
Contains an overview of CDAs and required materials for new CDA submissions.

Continuing Professional Education (CPE)
Offers guidance for CPE submissions.

Page updated: 4/20/2016
Clinical Trials F&A Cost Guidance

If you are searching for more general information about Indirect Costs (IDC) or Facilities and Administration Rates (F&A Rates) not specific to clinical trials, please visit our F&A page.

Clinical Trial F&A Flowchart

Clinical Trial F&A Rate Increased to 30% Effective July 1, 2018 - Announcement with Memo

Clinical Trial F&A Cost Guidance (PDF)

Industry-sponsored clinical trials are defined as "controlled clinical testing in human subjects of an investigational drug, device, or diagnostic (or comparison of drugs, devices, or diagnostics) to evaluate their safety and efficacy." (see Clinical Trials)

The University of Alabama at Birmingham’s (UAB) Facilities and Administrative (F&A) rate reflects the cost of real expenses that incur during the course of conducting research. These costs are classified as "indirect" because they are not easily identified with a specific project and do not appear as line items on budgets. Items that are included within the F&A cost rate are building and equipment depreciation; the portion of construction and facilities maintenance dedicated to research; recurring expenses such as utilities, telecommunications, hazardous waste disposal, security and fire protection, and liability insurance; institutional administration, which includes but is not limited to, accounting, legal, counsel, compliance, personnel, and sponsored programs administration; and research administration at the university, school, department, and division levels.

All industry-sponsored clinical trial agreements processed by the UAB Office of Sponsored Programs (OSP) should include the F&A rate of 30% to be applied for budgetary purposes, and ultimately on all cash received.

Page updated: 12/9/2018
Clinical Trial F&A Flowchart

Does this project meet UAB’s definition of a clinical trial for F&A purposes?

Answer the questions below to determine whether the project is eligible for the 30% rate.

1. Is the project laboratory research?
2. Is the project a retrospective chart review, a registry, or an observational study?
3. Is the project an analysis of existing data or medical records?
4. Is the project an animal study?
5. Is the project for services only?

If YES to any, then the project is NOT eligible for the 30% F&A Rate.

Yes / No?

If NO to all, then...

Does the project involve clinical testing in human subjects of an investigational new drug, device, treatment, or diagnostic according to a protocol to assess safety efficacy, costs, adverse reactions or outcomes?

OR

Does the project involve testing a comparison of approved drugs, devices, treatments or diagnostics in human subjects according to a protocol or assess safety efficacy, costs, adverse reactions or outcomes?

NOT eligible for the 30% F&A Rate.

Does the agreement give the sponsor the right to audit financial records?

Project is NOT eligible for the 30% F&A Rate.

Yes / No?

Project is eligible for the 30% F&A Rate.
Contact Information:

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ClinicalTrials.gov Update

May 16, 2017 May 17, 2017

Denise H. McKenzie, RN, BSN
Center for Clinical and Translational Science (CCTS)
Clinical Research Support Program (CRSP)
dhmckenzie@uabmc.edu
ClinicalTrial.gov: Penalties

- Penalties went into effect April 18, 2017
- Per the FDA (not new, now enforced with penalties)
  - $11,383 per infraction
  - If not corrected within 30 days, $11,383 per day thereafter
- Per the NIH
  - Loss of NIH funding for the investigator
  - Loss of NIH funding for the institution
  - Public listing of non-compliant investigators, clinical trials and institutions on the ClinicalTrial.gov website.
UAB Support Effective March 2017

- Friendly reminder emails sent beginning with the Primary Completion Date
- Communication becomes more critical 6 months post
- Results expected to be reported by the 10th month
- May require PI, Dept. Leadership, VPR, Research to determine a plan
- If warranted, further action from the Department
ClinicalTrials.gov: Required protocols

Per the FDAAA

- **Trials of drugs and biologics**: Controlled clinical investigations, other than phase 1 clinical investigations, of drugs or biological products subject to Food and Drug Administration (FDA) regulation

- **Trials of devices**: 1) Controlled trials with health outcomes of devices subject to FDA regulation, other than small feasibility studies, and 2) pediatric post market surveillance required by FDA

Per the NIH

- The policy applies to **ALL NIH-Funded Awardees & Investigators** conducting clinical trials funded in whole or in part by the NIH regardless of study phase, type of intervention, or whether they are subject to the statute and to the rule. (including phase I)
ClinicalTrial.gov: Responsibility Party

- Investigator-Initiated: Investigator will be responsible for registering protocol

- Sponsored: Pharmaceutical company is the responsible party and most often will register the trial (with study locations)
ClinicalTrial.gov: Future Changes

- Will Continue to evolve
- Uploading Documents
  - Protocol
  - Consent
  - IRB Approval
  - Statistical Analysis Plan
ClinicalTrial.gov: CCTS/CRSP Services

- Create an account
- One on one training with research teams
- Presentations for large groups
- Assistance with entering information
- Assistance with interpreting review comments
- Assistance with finding assistance!
- Contact ccts@uab.edu for training and support
- CCTS Website for CT.gov & UAB requirements and links
Questions?
UAB CRSP: General updates

Penelope M Jester, BSN MPH
Program Manager
pennyjester@uabmc.edu
Kudos to EVERYONE !!!

University training goal exceeded - 95% completion across campus

Important Notes:

- Effort certification for the 6 month period from October 1, 2016, through March 31, 2017, must be completed no later than May 30.

- If you have been assigned to take the training but have not completed, you will not be able to certify your effort report until this is completed.

- Know if your unit utilizes a pooled account.
At Risk Accounts/Pending Accounts: important notes

- Begin using immediately upon receipt.

- Reconcile prior study expenses for pre-award activities/costs as soon as the At Risk account is set-up.

- On a going forward basis, subsequent expenditures for study activities should be recorded in the study account at the time they are incurred.
SITE: Receive CTA

SITE: Submit to OSP with Extramural Checklist

OSP: Contacts Accounting to request At Risk/Pending Accounts (GA)

ACCOUNTING: Creates At Risk/Pending Accounts; notifies site (Note: Allow 2 weeks for receipt of account notification; notification goes to award manager)

ACCOUNTING: Activates account

SITE: Begins using At Risk/Pending Accounts (GA)

SITE: KEEP ON GOING!

OSP: Contract executed, notifies Accounting to make account active

REMINDER!!
Education! Where are we:

- **CITP**: Responsibilities and Implementation - for investigators: next session starts September 2017
- **ROP**: The Basics – all staff: next session May 25th 2017
- **RTP**: Implementation and tools for conducting research – support staff: next session Fall 2017
Research Seminar

• Last sessions will be in June (restart in September)
  • May 18: J Miller: UPDATE ON IRAP
  • June 1: PREPARING YOUR HSP APPLICATION WORKSHOP
  • June 15: BUILDING A BETTER BUDGET WORKSHOP

• Pending
  • CT.gov: Reporting Results WORKSHOP
  • Powertrials
  • OnCore
• Survey Monkey

• What you think and what you need matters!

• Please respond!!!

• Next CCTS Lunch and Learn: Sept 26, 2017
Education

• Questions?

• Contact:
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