Starting and Operating a Centralized Clinical Trials Office

Strategic Considerations Across the Organizational Life Cycle

Jamie Caldwell, Loyola University Chicago at the Medical Center
Sheila Lischwe, Saint Louis University

Association of Academic Health Centers Study

"Clinical Trials Offices: What's New in Research Administration"

2009

www.aahdc.org

Background/Rationale

Goal: Enhance revenues by becoming a preferred site among sponsors

- Operational efficiencies to speed time from contract initiation to study enrollment
- Coordination necessary between many different parties to ensure compliance (IRB, protocol development, billing);

Various Models of Organizing Business Functions

- Based on life stage of the CTO
- Based on individual institutional resources and culture

Primary Tasks Via the Life Cycle of a Clinical Trial

- education and training
- sponsor recruitment
- contract negotiation
- protocol development and approval
- budget development and approval
- advertising/subject recruitment
- regulatory compliance
- billing and billing compliance
- payment collections
- closeout

Mature Office - Loyola Model

The Clinical Trials Office was instituted to enhance the ability of the physician staff to carry out industry-sponsored clinical studies. The Clinical Trials Office function is to assist any physician in the conduct of clinical trials Including:

- Initial contact with industry sponsors
- Protocol development
- Regulatory document preparation and filing
- Budget preparation
- Investigators and staff training of the GCP guidelines

Clinical Trials Program

The goal of the clinical trials program is to conduct clinical trials of the highest quality standard. The program is staffed with dedicated registered nurses, who work with physicians, pharmacists and hospital staff to ensure accuracy in the conduct of clinical trials. This networking also makes it possible to gain referrals for studies. The program was initiated to:

- Increase the number and quality of clinical trials ongoing
- Assist departments that otherwise could not carry on clinical research
- Increase the capabilities of departments already staffed with research personnel to do additional trials.

Standard Operating Procedures (SOP's)

The institution encourages interactions and research with the private sector, and understands That such interactions are essential to achieving our mission and goals.

In general, sponsors of clinical trials are expected to pay all study-related expenses that are not covered by other third party insurers. Federal guidelines clearly indicate that certain clinical services provided as part of an industry sponsored clinical trial may be billed to government payers. There are also guidelines clearly stating that certain services which are not standard of care and thus are not billable to third party insure not be billed to study participants. In order to comply with these guidelines, investigators, coordinators and other individuals involved in health care operations processes must know:

- if a patient is participating in a study; and
- if the services they are providing are part of the study and/or standard of care.

In addition, there are certain start-up costs (IRB submission, budget preparation, and consent preparation fees) that must be included in all industry sponsored clinical trials research contracts and budgets.

Standard Operating Procedures (SOP's)- Cont.

Proposal Submission Requirements

When working towards the initiation of an industry sponsored clinical trial, a copy of the proposal/protocol provided to the IRB must also be submitted to the Central Clinical Trials Office (CCTO).

The CCTO will review the information and provide advice on modifications that may have to be made in the budget. The local standard of care indication is required for every clinical service provided.

Budget Preparation and Negotiation

Approval of the budget by the CCTO is required prior to an investigator's negotiation of financial terms with an industry sponsor. A budget preparation fee of $1,000 will be charged to all industry trials. The PI will retain this fee when the **detailed budget** is prepared by the PI (or his/her coordinator/business manager) and requires minimal review by the CCTO. If the PI requests the CCTO to prepare the budget, the fee will be retained by the CCTO, and the PI will be required to review and approve the budget as prepared. In addition, if the CCTO requires more than minimal time and effort (~ 1.5 hour) to review and correct a budget prepared by the PI's office, the CCTO will charge 50% of the budget preparation fee ($500).

IRB FEES

All industry-sponsored trials will be required to pay a one-time IRB fee of $3,000, which covers annual reviews and amendments. This fee is assessed by the Office of Research Services (ORS) for the review of protocols submitted to the IRB. The IRB does not set the fee, nor does it have the authority to waive the fee. This fee is not transferred to the CCTO. If the trial work is performed by the CCTO, the CCTO will bill the sponsor for the IRB fee as well as all other expenses related to the trial. If the trial is managed by a department, it is the department's responsibility to bill the sponsor for the IRB fee as well as all other expenses related to the trial. The Office of Fiscal Affairs will insure that the IRB fee is transferred to the IRB account from the initial sponsor payment.

Payment Processing and Budget Management

To ensure that appropriate internal controls are in place, new award account setups and all payment activity for industry sponsored clinical trials will be centralized in the Fiscal Affairs Office regardless of whether the CCTO or Department manages the project.

Consent Preparation

A Consent Preparation Fee is charged for all industry sponsored trials. This fee can be retained by the PI if the consent is prepared by the PI (or his/her coordinator/business manager) and requires minimal review by IRB staff. If the IRB staff requires more than minimal time and effort to review the consent (~ 1 hour), the IRB Office will charge 50% of the Consent Preparation Fee ($500). Alternatively, the PI may request that the consent be prepared by the IRB staff and pay the entire Consent Preparation Fee to the IRB Office. The Office of Fiscal Affairs will insure that appropriate payments are made to the IRB account.

Contract Review

All contracts for research must be approved by the Senior Associate Dean for Research after review by the ORS Staff Attorney. The proposed industry contract should be forwarded to the Staff Attorney (electronically with all necessary information as described on the Staff Attorney checklist) when the protocol is submitted to the IRB, thus allowing both reviews to occur simultaneously. The Staff Attorney will review the contract (excluding the budgetary component) and negotiate all terms with the industry sponsor. Once approved, the contract will be submitted to the Senior Associate Dean for Research, who will sign the contract after IRB approval and budgetary approval are documented.

Key Billing Concerns/Issues

- Standard of Care vs. Research
- Third Party Billing of Insurance
- Cost Standards for Government Sponsored Research
- Closeout

Billing Compliance Activities

- Perform Risk Assessments on all Projects
- Sample Billing Reviews
- Track Staff/Patient Billing Complaints
- Ensure Correct coding on claims

Closing Out Your Trial

- Financial Closeout
- Obligations
- Retention of Records

Planning/New Office SLU Model

- Historically decentralized departmentally
  - Contract Review housed in Pre-Award
- Problems with reporting - only know the value of the contract
- Budgeting done separately by department
- Inefficiencies slow down process

Planning/New Office

- Political Climate
  - New SOM Dean, Associate Deans for Basic and Clinical Research, Internal Medicine Chair, Vice President for Research
- White Paper Exploring Advantages/Disadvantages of Centralizing Function
- Personnel Changes
- Electronic Management of Data
- Office Move

New Office Creation

- Use existing, re-purposed SoLUtions unit
- Management moved to Assistant Dean for Clinical and Translational Science
- Required Use of Centralized Services
- Pods – Inefficient pods will be moved to efficient pods for cost-effectiveness
- Centralized advertising, regulatory compliance, budget development, billing, compliance coordination

Challenges

- Administrative
  - Sign off of contracts
  - Lack of attention to detail to standard operating procedures – business plan
- Leadership
- Communication of Change

Discussion – The Big Questions

- To mandate use or not?
- How to co-exist with departmental structures?
- Understanding the political climate
- What's it going to cost? Innovative ways to support the function…

Mandate Use?

- Advantages
  - Standardization
  - Efficiencies
  - Improved Cost Structure
  - Reduces Time to Study Initiation
  - Enhanced Compliance
  - Accurate Reporting
- Disadvantages
  - Morale
  - Fear of Job Loss
  - Volume in central office

What's It Going to Cost?

- Using existing resources
- Building in support for contract review into the budget

Questions?

Jamie Caldwell, MBA
Director, Office of Research Services at Loyola University Chicago at the Medical Center
Phone: 708-216-2636
jcaldw@lumc.edu

Sheila Lischwe, Ph.D.
Director, Office of Research Services
Saint Louis University
Phone: 314-977-7742
lischwst@slu.edu