Research Administrators
Monthly Meeting
October 2018

Peggy Diskin, Associate Director (Proposals)
Office of Research Services
Agenda

▪ Announcements
▪ Clinical Trial Budget Basics
▪ Questions/Discussion
Announcements

- Proposal Team Contacts
- Thank you Beth!
Clinical Trial Budget Basics

Identify the Components of a Clinical Trial Budget

Identify the hidden costs
Initial Contact from Sponsor

▪ The sponsor reaches out to potential sites to determine interest and feasibility for conducting a trial.

▪ A pre-study questionnaire may be requested to summarize potential for patient recruitment, staff availability, and existence of needed equipment.
Where Do I Start?

What you need:

- The Protocol
  - schedule of events
- The sponsor draft informed consent
- The sponsor draft budget
- The sponsor draft contract
## Schedule of Events

**Epidural Neuromodulation for Spinal Cord Injury**

**Protocol #**

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### Table 2

**Procedures**

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*Items are grouped according to the major categories of 7.1.1 in blue. Categories containing elements administered at different times in the study are expanded and grayed out. ‘X’ represents mandatory assessments for all subjects. ‘a’ represents assessments for subjects selected to undergo autonemics protocol.*
Coverage Analysis

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<th>Items and Services</th>
<th>Protocol Location</th>
<th>CPT/ICD Code</th>
<th>GPO/Provider Code</th>
<th>Pre-screening</th>
<th>Treatment Phase (200 Days Post Randomization)</th>
<th>Post Treatment</th>
<th>Comments</th>
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*Time & Effect*

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*Evaluation & Management Services*

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*Notes:*
- This Coverage Analysis is intended as a general guideline for use in determining which items and services are billable to Medicare/Medicaid payers based upon current benefit policies, coverage determinations, coverage decisions, and physician determinations. All items and services designated as billable must be supported by medical necessity.

*Additional Notes:*
- Items marked with an asterisk (*) may require additional documentation for medical necessity to be billed at a higher rate.
- Items marked with a double asterisk (**) may require additional documentation for medical necessity to be billed at all.
- Items marked with a triple asterisk (***) may require additional documentation for medical necessity to be billed at a lower rate.

*Frequent Changes:* Items and services may be added, deleted, or modified at any time. Providers are advised to consult with their billing department for the most current information.

*Billing Tips:* Providers are encouraged to submit claims in a timely manner to avoid delays in reimbursement. Providers should verify that all required documentation is included with the claim.

*Provider Support:* Providers are encouraged to contact their assigned billing representative for any questions or concerns regarding billing and reimbursement.

*Provider Responsibilities:* Providers are responsible for ensuring that all required documentation is included with the claim. Providers should verify that the services rendered are consistent with the coverage requirements outlined in the protocol.

*Medical Necessity:* Providers should ensure that the services rendered are medically necessary and consistent with the treatment plan outlined in the protocol. Providers should consult with the appropriate medical authority for any questions or concerns regarding medical necessity.

*Billing Guidelines:* Providers should follow all applicable billing guidelines and regulations to ensure accurate and timely reimbursement.

*Medical Record*: Providers should maintain accurate and complete medical records to support medical necessity and consistency with the treatment plan.

*Billing Coordinator*: Providers should coordinate with the billing department to ensure timely submission of claims and accurate reimbursement.

*Billing Resources:* Providers are encouraged to utilize available billing resources, such as billing manuals and online resources, to ensure accurate and timely reimbursement.

*Financial Responsibility:* Providers are responsible for ensuring that all required documentation is included with the claim. Providers should verify that the services rendered are consistent with the coverage requirements outlined in the protocol.

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Process for building a budget

Industry Sponsored Budget Components

- Personnel Costs
- Procedures
- Labs
- Pharmacy Fees
- Subject Stipends
- Overhead
Process for building a budget

Personnel Costs

- Study Personnel – need “effort” estimates by time (mins/hrs/per visit) and typical personnel and their estimated salary/benefits (MD Investigator, clinical study coordinator (RN), non RN trial coordinator, …) for each item on the Schedule of Events (SOE)

- Effort must include salary and fringe benefits

- UIC FY19 Fringe Benefit Rate: 35.15%
Process for building a budget

Procedures

Labs

Obtain research rates for each clinical procedure

- Laboratory fees
  - Lab panels vs. individual tests
- Central labs vs local labs
- Overnight shipping
- Radiology
- Clinical supplies
- Pharmacokinetics
  - Serial collections
- Tumor Tissue Collection
  - Fresh Tissue vs. Archival Tissue
Process for building a budget

Pharmacy Fees

Study Drug and Administration

- Infusion vs. IV push vs. Subcutaneous Injection vs. Oral
- Provided by Sponsor vs. Commercially Available
- Dispensing and storage charges

Contact the Investigational Drug Service at UI Health
Process for building a budget

Subject Stipends

- Meals
- Transportation
  - Site Provided or Mileage Reimbursement
  - Parking Stickers
- Sponsor may pay study subject directly
Process for building a budget

Don’t Forget to Consider...

- Study Start-Up
  - Staff Training
  - Recruitment Activities
- Staff Time
  - Review of Serious Unexpected Serious Events (SUSAR)
  - Investigational New Drug (IND) Reports
  - Remote Monitoring
    - Upload Documents
  - Archive document storage fee $ rate /year for 7 years
  - Source document binders per subject
Process for building a budget

Don’t Forget to Consider. . .

- IRB Review
- IRB Continuing Review Fee
- IRB Amendment Review
- IRB Preparation Fee
Process for building a budget

Overhead on Industry Sponsored Clinical Trials

Indirect Cost Rate (IDC) for Industry Sponsored Studies

The UIC indirect cost rate of 25% TDC (Total Direct Cost Base) applies to ALL procedural and non-procedural line items, as well as, to items that must be invoiced.
Process for building a budget

Budgeting for Federally Funded Clinical Trials

- Effort covers all PI’s work, including professional fees for clinical services and procedures.

- Clinical procedures are to be priced at the research rate for Governmentally-funded research (obtain from UI Health Research Administration).

- General administrative expenses should not be included as direct costs on the budget.

- Use current applicable fringe benefit rate (35.15%) and F&A rate (59.9% MTDC).
Process for building a budget

NEGOTIATE NEGOTIATE NEGOTIATE

- Prepare in advance
- Negotiate
- Be prepared to walk away
Why is all of this important?

As a non-profit institution, UIC must recover the full cost of research conducted for outside sponsors, including all associated operating costs (overhead). To do otherwise would result in subsidizing for-profit research and could jeopardize the institution’s non-profit status.
Clinical Trials at UIC

For Externally Sponsored Clinical Trials (Industry sponsored/Federally funded/Private Foundation funded)

- Coverage Analysis
- Clinic/Hospital Request for Services Form
- IRB Application
- ORS contract review
- Clinic/Hospital Research Services Billing - study participants need to be placed on the research bill hold
Clinical Trials at UIC

For Principal Investigator (PI) Sponsored Clinical Trials or Department Funded Clinical Trials (no external funding or third-party sponsor)

- Coverage Analysis
- Clinic/Hospital Request for Services Form
- IRB Application
- Clinic/Hospital Research Services Billing - study participants need to be placed on the research bill hold
UIC QUESTIONS

UIC Clinical Trials Website: http://research.uic.edu/ct

- Coverage Analysis: covanlysis@uic.edu
- Clinic/Hospital request for services: scottken@uic.edu
- Clinic/Hospital budget review: scottken@uic.edu
- Clinic/Hospital research services billing: scottken@uic.edu
- Contract Review: awards@ic.edu
Questions/Discussion
Next Meeting

Wednesday, November 28th from 1-2pm

Topic:
Subawards and Sub-recipient monitoring