Industry Sponsored Clinical Trial Budgets
Signe Denmark, Research Opportunities & Collaborations
Objectives

- Review the planning steps for building a research budget
- Compliance & Fair Market Value
- Obtain research pricing
- Utilize the Industry Template
- Tips for the budget negotiation process
What is a clinical trial budget?

- Estimate of costs required to perform the research scope of work
- Financial plan for the project
Feasibility & Planning: review the protocol with the PI and research team to conceptualize study start-up, conduct, and closeout. Develop the budget based on the estimate of costs associated with completing study obligations. Negotiate the budget with the sponsor. Route the draft Clinical Trial Agreement (CTA), final sponsor budget, ORSP budget, and protocol to ORSP via ePDS. PI signs the final CTA and ORSP executes the document and releases IRB approval (or submission to WIRB).
Feasibility & Planning

- Who will perform protocol related procedures, research coordination, recruitment, regulatory, store/dispense investigational product (IP)
- What additional services/approvals/equipment/training may be required?
- When will the study begin and end?
- Where will the study be conducted, do we have the space?
- Which IRB will be utilized?
- How will you reach the study’s recruitment goals?
Planning

- Dissect the study protocol schedule of assessments, description of study procedures, inclusion/exclusion

- SCTR Research Support Fee for Service Programs
  - Research Nexus
  - Research Coordination & Management

- SPARC Request
  - All pricing for CPT coded services, professional and technical fees
  - 30% corporate discount is applied to professional fees (provider services)
  - For CPT codes not found in SPARC email sparcs-picquestions@musc.edu with CPT code
  - Set up study in SPARC for research billing compliance and patient safety

- Understanding MUSC policies and procedures

- Internal Budget Template

SCTR
South Carolina Clinical & Translational Research Institute
Budget categories

- Site level costs
  - Start-up
  - IRB fees
  - IDS fees
  - Study maintenance costs
  - Close out costs

- Per subject costs
  - Protocol procedures
  - Administrative activity
  - Research facility fees

- Personnel costs

- Other budget Considerations
Standard of Care (SOC) vs. Research Costs

- Standard of Care/Routine Care is a service listed in the protocol that would be provided to the patient even absent a clinical trial; these are medically necessary services.

- Non-covered services/non-routine services must be budgeted for in the clinical trial as a cost to the sponsor because:
  - They are services not normally covered by insurance.
  - They are services performed specifically because they are required in the protocol to collect data (for example, performing EKGs at a greater frequency than medically indicated to fulfill the requirements of the protocol).
  - They are services performed to screen patients for participation in the trial.
  - They are services that cannot be billed to insurance because they are listed in the budget for the trial as an expense of the sponsor.
Per Subject Costs: Compliance

- Medicare Coverage Analysis – WHY?
  - Medicare will only pay for services considered “Routine Costs” of Clinical Trials
  - Local Medicare contractors set rules of coverage that limit what services will be paid by insurance. These rules impact the study budget directly.
  - Knowing ahead of time what budget items will be covered by insurance allows Coordinators to work with Sponsors so that all services are paid.
  - Neither the patient nor the hospital suffers unnecessary cost.

- No “double dipping” (billing insurance when research services should be covered by research grant funds)

- Contact University Compliance at 2-8740
Fair Market Value (FMV)

  - Payments for research services should be FMV for legitimate, reasonable, and necessary services
  - Did not specifically define term or parameters to determine FMV

- Other noteworthy regulations affecting FMV practices
  - Federal and state regulations
  - Professional codes of conduct
  - Federal Anti-Kickback Statute
  - Stark Laws (42 Code of Federal Regulations Parts 411 and 424 regarding physician referrals)
  - Physician Payment Sunshine Act
Budget development has been a challenging task to both sites and sponsors for decades... Unfortunately, sponsors and sites continue to wrestle with understanding the fair market value (FMV) of medical services. Confusion is widespread over the definition of FMV, with many sites and sponsors struggling to correctly apply the concept when developing a study budget.”

Fair Market Value (FMV) – Sponsor

Applied Clinical Trials Aug 1, 2014:

“Pharmaceutical, medical device, and diagnostic companies are required to comply with the FMV stipulations, but the federal regulators do not provide advice on the determination of FMV for medical services. This places sponsors in an ill-defined situation fraught with potential legal and financial risk. . . Industry sponsors are cognizant of the regulations and strive to follow published FMV requirements. In order to remain compliant with the regulations, many sponsors desire documentation to support the pricing of medical services in a clinical study budget. Unfortunately, most sponsors do not have access to realistic FMV pricing information. The lack of real pricing information commonly results in sponsors’ frequently employing two inaccurate pricing strategies—Medicare pricing and benchmark pricing.”
Fair Market Value (FMV)

- Benchmark databases (Medidata Grants Manager® and TTC GrantPlan®)
  - Procedure costs
  - Overhead rates
  - Other direct costs
- Based on CPT coded procedure costs
- A primary tenet of FMV is a "willing buyer negotiating the purchase price with a willing seller"
Successful budget

- Expenses = Revenue = Breakeven
- Expenses < Revenue = Residuals
  - Projects with residuals greater than 25% of the total project revenue may require explanation
  - [http://academicdepartments.musc.edu/vpfa/policies/grants/4-4.02.htm](http://academicdepartments.musc.edu/vpfa/policies/grants/4-4.02.htm)
Budgeting Case Study

- 20 sites enrolling 360 subjects, competitive enrollment

- Study timelines
  - 3 month study start up
  - 6 month enrollment
  - 12 month follow up
  - 3 month closeout
Budgeting Case Study

- Number of patients: 18-20
- Project period: 24 months (18 based on sponsor + 6 months)

Personnel
- PI/Co-I/Coordinator
- Institutional base salary & FB x % effort
- $75,000 (based on effort and period of time)
Develop your budget

- When will the study begin and end: 12/1/2014 through 12/1/2016
- Where will the study be conducted: Nexus
- How will you reach the study’s recruitment goals?
  - Clinic database
  - Clinical Data Warehouse (CDW) honest broker research query
- What additional activities/services/approvals may be required?
  - Nexus inservice
  - CDW Honest Broker review and approval
  - Continuous ABC monitoring
- Obtain pricing
  - SPARC Request for CPT coded and SCTR research services
  - Personnel salary information
  - IDS pricing spreadsheet
  - Phase 2 so local IRB fees apply
## Internal & External Budgets

### Internal
- Actual costs/activity
- Contingency funds
- Project period
- Personnel effort
- Breakeven analysis
- Indirect cost on ALL costs
- Max compensation calculation for ORSP

### External
- Charges to sponsor
- No profit
- Sponsor format
- Mark up
- Indirect cost
Budgeting and Negotiation Tips

- 70% Calculations
- 30% Interpretation/Experience/Intuition
  - Renegotiate
- The sponsor budget is a proposal, you do not have to accept it
- Obtaining a realistic recruitment number is key
  - Feasibility process
  - When enrollment goals are consistently met or exceeded, this improves
- Be prepared to provide justification for costs
- Sponsors just want to know what they are paying for
SUCCESS Center Consultations

- Grants & Budget Development
- Regulatory Knowledge and Support
  - Hands on training and consultation
  - State-wide eIRB project management
- Participant Recruitment
  - Strategies, planning & partnerships
  - Budget
  - Materials
- SPARC Request Hands on Training
- Research Navigation

SUCCESS Center Staff, 2013

SPARC Request Hands on Training
SCTR Research Nexus Consultations

- Research Coordination & Management (RCM)
  - RCM Coordinator time and cost estimates
  - Full, gap or partial services

- Research Navigation Consultations
  - Protocol Review (nursing)
  - Laboratory Consultation

- Standard of Care Services
  - Medical University Hospital Authority provider based clinic
  - Ability to bill 3rd party payers (insurance companies) for SOC services provided during research visits
  - Increased satisfaction for participants, investigators and research teams
  - High quality continuum of care provided in one location
Questions?

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