

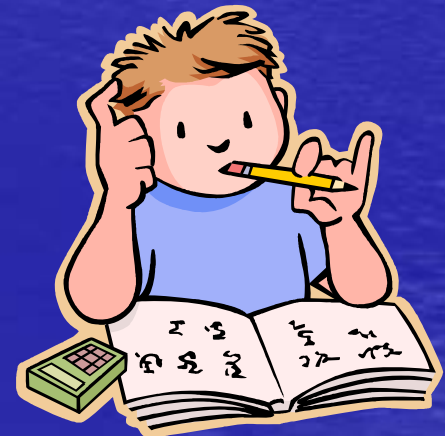
# Developing Clinical Research Budgets

# Agenda

- Importance of accurate budget
- Protocol Review
- Evaluating the Sponsor's Budget
- Developing the Internal Budget
- Reviewing the Payment Schedule
- Additional Budgeting Considerations
- Relations with sponsors – the negotiation processes

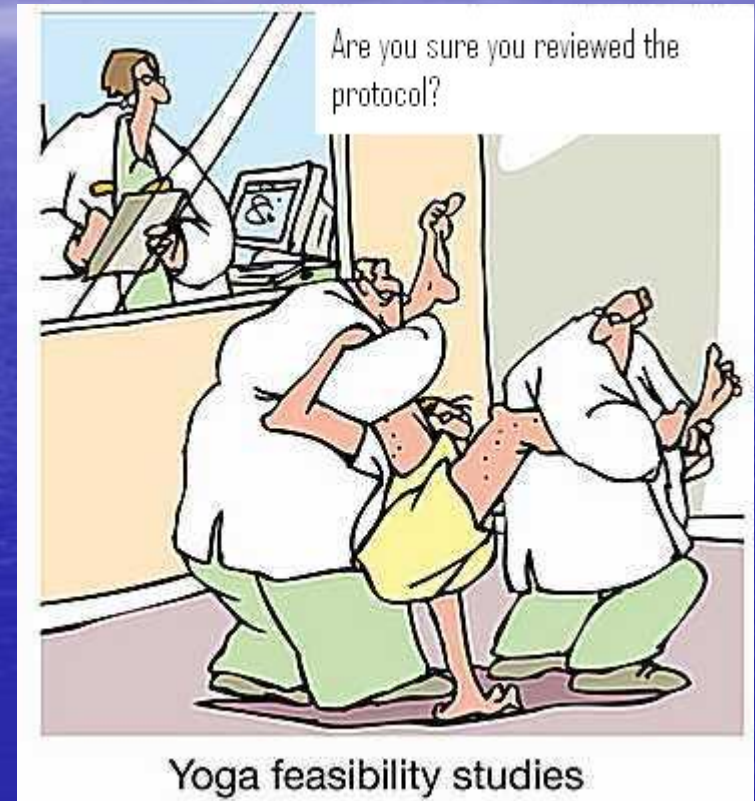
# Importance of Accurate Study Budgets

- Ability to cover all expenses
- Credibility with Industry, Institution and PI
- Risk of loss of staff
- Start up costs



# Protocol Review

- Purpose of the study
- Investigational Plan
- Schedule of Events
- Visit Schedule
- Inclusion and Exclusion
- Schedule of Laboratory Tests
- Informed Consent



# Where Do Sponsor's Budgets Come From?



# Types of Sponsor Budgets

- Flat amount per patient enrolled
  - eg \$8,000 per enrolled patient including indirect costs
- Prepared Budget
  - Dollar amount is attached to each service and procedure
  - References schedule of events and procedures
  - Includes PI and RC costs
  - Indirect costs are usually a separate line item

# Internal Budget

- Standard Costs
  - REB fee
  - Start up Fees (One Time Fee)
  - Storage Fees
- One Time Fees
  - Pharmacy Review Fees
  - Laboratory Review Fees
- Pass Through Fees
  - Medical Records Fees
  - Safety Report Preparation and Review

# Internal Budgets

- Indirect Costs (Facilities and Administration Costs)
  - Driven by Institutional Policy and Agreements
    - Vary according to the type of support
      - Governmental
      - Investigator Initiated
      - Pharmaceutical (Industry)
      - Grant
      - Foundation

# Internal Budget: Start Up Fees

- Feasibility Meeting
  - Coordinator (2 hours), Investigator (1/4 hour)
- Protocol Review
  - Coordinator (4 hours), Investigator (1.75 hours)
- Contract and Budget Review
  - Coordinator (5 hours), Investigator (3/4 hour)
- REB Document Preparation (5 hours)
- Regulatory Document Preparation (3 hours)
- Project Start-up Preparation (5 hours)
- REB Response (1.5 hours)

# Internal Budget

## Start Up Fees con't

- Study Initiation Meeting
  - Coordinator (4 hours), Investigator (1 hour)
- Sponsored Projects Administration
- Investigator's Meeting
  - Time away from the office
    - Coordinator and Investigator (12 hours)
- Training
  - Clinical Staff, Hospital Staff, Physicians, Coordinators

# Internal Budgets: Human Resources

## Study Coordinator/Research Nurse

- Investigator Meeting
- Recruitment
- Screening
- Consenting
- Randomization
- Review of diaries
- Pill counting
- Coordinating visits
- Study visit time
- CRF completion
- Maintenance of study files and Regulatory binder
- SAE reporting
- Monitoring visits
- Communications with monitor and sponsor
- Resolving Queries
- Closeout Visit

# Internal Budgets: Human Resources

## Study Coordinator/Research Nurse

- Study Related Procedures
  - PK Studies
  - Infusions
  - Administration of study drug/device
  - IV starting
  - Blood draws
  - Vital signs
- Investigator Delegated responsibilities
- Collection and storage and shipping of samples
- Processing samples

# Internal Budgets: Human Resources

## Investigator/Physician Charges

- Physician Charges
  - Physical Exams
  - Procedural Fees
  - PI fees
  - CRF/source documentation review
- Ancillary Charges
  - Radiology
  - Laboratory
  - Pulmonary
  - Cardiology
  - Pathology

# Internal Budgets: Other Considerations

- Complexity of study
  - Careful review of referral base for study patients
  - Careful review of inclusion and exclusion criteria
- Length of study
  - Short term vs long term follow up
- Resources
  - Human and Supplies
- Stipends
  - Patient reimbursements and any participant payments

# Payment Schedule

- What Triggers Payments
  - Start-up costs, REB fees usually at contract level
  - CRF completion
  - Number of patients enrolled
  - Completed patient visits
  - Screen failures
  - Conclusion of the trial

# Payment Schedule

- Ensure the contract specifies when the first payment occurs and what triggers others (ie start up, first complete patient)
- Payments based upon CRF completion
  - Dependent on monitor
  - Submission to data management
  - Query resolution
- Payments based upon number of patients
  - Recruitment costs?
  - Screen failures?
  - Each patient enrolled
  - Block payments (ie first 5 or 10 patients enrolled)

# Payment Schedule

- Payments based upon number of completed visits
  - Payments received in a reasonable time
  - Study doesn't run into deficit
  - Screen Failures (payment based upon costs incurred or procedures completed)
- Payment at conclusion of study
  - Study has cash flow problems
  - Delays in payments

# Additional Budgeting Considerations

- Percentage withheld (usually until study completion)
  - Percentage should be small (~10%)
- Early Termination of Patients
  - Payment based upon completion of study visits and procedures

# Ideal Payment Schedule

- Non-refundable Start up Payment
- Regular payments with realistic milestones
- Final payments made at close-out
- Invoicing allowed for other costs
  - Advertising
  - Travel
  - Equipment

# The Art of Negotiation



# Negotiations with the Sponsor

- Plan and Prepare
  - Identify potential issues ahead of time
  - Understand the importance of the issue
  - Know the must haves, the wants and the what costs you are able to reduce
- Set the Tone
  - Communicate clearly
  - Be fair
  - Remain courteous
  - Be firm
  - Be flexible

# Negotiation with the Sponsor

- Summarize the Agreement
- Don't be afraid to re-open the negotiation