Putting a budget together….where do you start?

- Center for Clinical Studies
- Phyllis Klein, RN, CCRC, BSN
- Director, Regulatory, Compliance & Support
- (314) 747-4289
Study Budget Development

- Read the protocol
- Determine what services you need to provide
- Are any of these services considered standard of care (SOC)?
- Identify those that are needed for the research only
Study Budget Development

- Review the schedule of assessments
- Compare it with the protocol requirements
- Determine how long you will need to be with the patient
- What paperwork needs to be done when the patient leaves?
Study Budget Development

- Affix a cost for each study-related procedure
- Obtain a price quote with a research discount for those procedures that you will not be able to complete on your own
- Determine a cost for time spent (hourly) for the coordinator/physician
Study Budget Development

- Don’t forget your one-time costs
  - IRB submission fees
  - IRB Preparation/Regulatory fee
  - Research Pharmacy fees
  - Long-Term Document Storage fee
  - Per patient PI fee
Study Budget Development

- How about equipment charges?
  - ECG machine/per use
  - IV pump use/per infusion
  - Pump tubing
  - Anything else?
Study Budget Development

- Don’t forget to account for
  - Patient stipends
  - Parking stamp fees
  - Mileage
  - Taxi’s fees
  - Hotel charges
  - Monitoring time
SOC versus Investigational

- Any charge in your study budget cannot be billed to another source.
- If standard care dictates, and the procedure will be paid by patient insurance or Medicare, then you cannot have the cost in your study budget.
- If the informed consent says the patient will not pay for certain services, then they cannot be charged, and neither can their insurance company or Medicare.
Patient Costs

- Patients are responsible for any co-pays or deductibles that are part of their insurance plan.
- We CANNOT reimburse the cost of the co-pays or deductibles even if the study is supposed to cover the cost of the procedure.
- If covered by the study budget, you MUST pay for the entire procedure from the study funds—you cannot allow the patient/insurance company or Medicare to pay for the procedure.
- BJH & WU offer research discounts for study procedures and professional fees.
Study Budget Development

- Sponsor’s usually have a little wiggle room on their budgets...
- I have been told it’s about 30% before they have to go for approval to the next level! Don’t be afraid to ask for a little more, all they can say is no!
Contacts - BJ H

- BJ H – for any procedures at the hospital
  - Moshe Shtengel  362-0879
- BJ H Research Pharmacy
  - Julie Nobbe  454-7331
  - Kathryn Vehe  362-3376
Contacts – SLCH

- **Lab Prices**
  - Call 454-2750

- **Radiology Prices**
  - Paula Vice 454-6235

- **Heart Station**
  - Tim Sekarski 454-6177

- **Research Pharmacy**
  - Liz Jordan 454-6014
Contacts - WU

- In order to get the cost of professional fees for your study procedures, you will need to call someone in the department providing the service for prices.
- We have no central area to coordinator pricing at present.
- The FPP has agreed to a research rate for professional fees of 1.8 times the 2005 Medicare rate for industry sponsored studies.
Study Budget Development

- Questions?