Developing A Clinical Research Center

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What Led Us to Establish A CRC?

- Increase in the availability of clinical trials funding nationwide
- Regulatory Demands
- New VA Initiatives in Clinical Research
- Pressure by VA to Reimburse the Appropriation (Making it Whole)
Purpose of Center

• To develop an organization that can sell its infrastructure to potential clients to further advance research
• Increase communication and minimize bureaucracy
• Train Clinical Coordinators
Purpose of Center (cont.)

- Ensure compliance of regulatory guidelines
  - FDA Audit
  - HIC/IRB Review
  - AAHRPP
  - Monitor Visits
  - Site Visits
Purpose of Center (cont.)

- Centralization of Services
  - Physical area for center
  - Data Management
  - Pharmacy
  - Lab Services
  - Clerical Time Back to Coordinators
Process of Establishing a CRC

- Board Approval of Concept
- Hire a Research Pharmacist/Assistant
- Hire Clinical Research Manager/Director
- Hire Human Studies Analyst
- Hire Medical Director (At least 5/8th)
- Develop relationship with HCIS (electronic Records/Clinics)
Process of Establishing a CRC

- Visit other centers (INSITE, BREF)
- Interview P.Is. and Coordinators
- Interview IRB
- Interview Monitors
- Interview Ancillary Services
Results of Interviews

• Positive Points
  – Facilitate the protocol approval process
  – One Source to answer all questions
  – Standardization of procedures
  – Education and training
  – Centralization of Clinical Research Services
Results of Interviews

- Perceived Negative Points
  - More paperwork
  - Cost increase in procedures and overhead fees
  - Resistance to change (why do this, things are great)
Schedule

- Where we are today
  - people
  - equipment
  - resources
  - medical center negotiations
  - business plan
Schedule

• Where we want to be on 1/1/2007
  – People – Relook at coordinators
  – Equipment - Phlebotomy
  – Resources – Refocus on Grants