Developing the Plan for Conducting a Study Safely and Efficiently

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July 24, 2013

Areas to Consider

- Creating, training and managing your research team
- Patient recruitment strategies
- Quality control
- Data management
- Data analysis
- Research participant safety
- Financial management
Research Team

- Principal investigator
- Co-investigators
- Project director/clinic coordinator
- Recruiter
- Research assistant/clinic staff
- Quality control coordinator
- Data manager
- Programmer/analyst
- Statistician
- Administrative assistant
- Financial manager
- Human resources manager

Training of Research Team

- Are clinical credentials needed for task?
- Is protocol complete and clear concerning who does what?
- Amount and type of training
  - Formal training and retraining
  - Complete test
  - Communication and handoffs
  - Observe performance
Training of Research Team

- How to respond in an emergency
- Create checklists
- Consider simulation center
- Documentation of training

Standardized Operations

- SOP: Standard Operating Procedures
- Operations manual
- Data collection forms
Recruitment

• Approaching patients (HIPPA)
• Advertising
  – Needs IRB approval
  – Newspapers and more unique venues
  – Internet and social media
  – Press releases
• Working with patient advocacy groups
• Consider complexity of trials
• Developing best practices
CRMS Study Participation by Zip Code – Per 1,000 of Population

CRMS Study Participation by Zip Code – Per JHH Patients*

* Unique Patients at The Johns Hopkins Hospital (FY10 – FY12) – Inpatient and Outpatient
Quality Control

- Who is doing the study measurements?
  - DATA QUALITY IS PRIORITY
- How are study staff being trained and monitored for quality over time?
- Is equipment being calibrated?
- What about data entry?
  - Avoid hand copying of data if possible
  - Duplicate data entry

Data Management

- Check for any common vocabularies and data definitions
- Data collection through self-report, interview or direct computer entry, scanable forms
- Data security
  - Auditing viewing, entering and changing data (CFR 11 compliance)
  - Any research data on portable device must be encrypted and password protected
- Backup of data
- Sharing of data
- Working with multicenter coordinating center
Biospecimens

- Consent
- Safe handling
- Appropriate processing and storage
- Transfer
- IT support caTISSUE

Clinical Research Management System

Key:
- Currently In Use
- Work In Progress
- Possible Future Functionality
Research Participant Safety

- Develop an overall safety plan starting with identification of biggest risks
- Consenting process and storage of consent forms
- Research staff training and “culture of safety”
- Monitoring for adverse events, grading events and process for reporting
  - Need for Data and Safety Monitoring Board
- Safe dispensing of research medications
- Management of “incidental” findings
- Research participant advisory boards

Project Management

- Develop a reasonable time line for study activities
- Determine dependencies – what has to be done first?
  - Ex, Need for engaging FDA on IND consult
- Think ahead to sharing findings through abstracts, publications and forums
Summary

• Valuable study requires excellent execution
• Written SOPs and data use agreements always helpful in preventing and resolving conflicts
• Ask for help from experienced faculty and research staff