Investigator Training Program
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The Mechanics of Performing a Clinical Trial

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In Summary….

• Clinical trials are partnerships between sponsor, local review boards, site investigators, and staff.
• Attention to detail and close adherence to study procedures are essential to success.
• At the site level, success or failure of a trial is in the hands of the investigator with assistance from a trained Clinical Research Associate.
• When conducted with sufficient resources and training, clinical trials can be rewarding experiences for investigators and patients.
Clinical Trial Process Overview
Start to Finish

- Pre Award and Initial Decisions
- Study Start-Up
- Trial Progression
- Study Close Out
Pre Award and Initial Decisions

- Delegation of Responsibilities: **Your Team!**
- Protocol Review: Time, Scheduling, Data Requirements
- Budget Review: Verify Costs, Preparation and Approval
- Contract Review: Preparation and Approval
- Resources
  - Institutional Review Board (IRB)
  - Institutional Biosafety Committee (IBC)
  - Radiation Safety Committee (RSA)
  - Committee for the Humane Use of Animals (CHUA)
  - Quality Assessment & Improvement Program (QAIP)
  - Research Development Office
  - Sponsored Programs and Clinical Trials Office (CTO)
  - Center For Outcomes research and Evaluation (CORE)
Study Start-Up

- Staff Delegation of Responsibilities: Your Team!
- Timelines and DEADLINES!
- Collaborative Institutional Training Initiative: CITI
- ICH/GCP Training
- SOPs
- CTO Required Start Up Documents: College Face Sheet (P/A/T#)
- IRB Application Process
- IRB Review Process
- Regulatory Document Requirements
- Site Initiation Visit: Sponsor Training
- Clinical Administrative Information System (CAIS) IMT

Billing Insurance for payment of services that meets the guidelines established by Medicare, Medicaid or any other payer as “research” is a fraudulent
Study Start-Up

• Clinical Research Billing: CAIS: Standard of Care/Research
• Recruitment Plan
• Access to Patient Information and Electronic Data for Research
• UH Pharmacy Based Investigational Drug Service (IDS)
• Location of Study: CRU/Hospital Based/MSG Private Office/Satellite Offices/Other: Educational In-service
• Require other Departments’ Collaboration
• Laboratory Requirements: Central Lab/Clinical Pathology
• Space
• Research Meetings: Sponsor Investigator Meeting/Routine
• Administrative Tasks: Email/Correspondence/Phone/Filing/Copying
• Relationship with Sponsor/Monitor: Point Person
• Additional Training Requirements
Clinical Trial Progression

• Recruitment
• Informed Consent Process ---ongoing interactive dialogue beginning at enrollment and continuing until participation is complete
  Stamped IRB Approved ICF: most current approved version of ICF
• Ongoing Communication with Subject
• Motivation of Staff and Subjects
• Source Documentation: Collecting, Compiling, Organizing
• Completing Case Report Forms/Electronic Case Report Forms
• Receipt and Review of Off site Results i.e. Lab results, ECG central reader, etc.
• Notes to File
• Ongoing Regulatory Document Maintenance
• Electronic Data Capture System Entry Deadlines
• Query Resolution Deadlines
Clinical Trial Progression

- All Protocol Changes/Amendment Submission to IRB
- Annual Continuing Review Submission to IRB
- IRB Acknowledgement of Receipt Submission
- Data Safety Monitoring Board (DSMB) Submission to IRB
- Protocol Deviations/Violations Reporting to IRB
- Unanticipated Problems and Adverse Event Reporting to IRB
  - Internal Events/External Events
- Event Reporting to Sponsor: SAE/AE
- Billing Review Weekly
- Research Meetings: Information Exchange
- Equipment Needs/Supplies/Ordering
- Routine Monitor Visits
- Audits
- Organize.....Organize...Organize
- Periodic Review of Best Practice Procedures
- Regulatory Education and Updates: SoCRA, ACRP, “Hot Topics”
Study Close Out

- Termination of conduct of the study
- Sponsor Close Out Visit: Intense Document Review
- Archiving Records
- Drug Accountability/Destruction Policy
- Equipment
- Lab supplies
- IRB Notification: Termination Request Form
- CTO Notification: Post Award Review
- Fiscal Services Notification
- IMT Notification: Verify Removal from Master CAIS System
- Research Accounting Notification
- Review billing/funding to assure all bills have been paid and all funding received
- Verify transfer of any remaining funds to MSA
Study Close Out

• Team Recap and Review….the positives….the not so positives
• Where is there room for improvement?
• And…..
Concurrent Clinical Trials
The Mechanics of Performing a Clinical Trial…