An Approach to Quality Management in an Academic Setting
Disclosure

We have no financial relationship relevant to this educational activity

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Objectives

• Identify four components of Quality System Management
• Understand the application of the QSM
• Evaluate the Effectiveness of QSM
Ochsner Clinic Foundation

• Network of Hospitals and Clinics
• Academic Medical Center
• Clinical, Tranlational, Nursing, and Outcomes Research
Research Quality Assurance

• History of Program Development
• Research Reviews
• Lack of Trend Analysis
• Lack of Reinforcement of Quality Improvement
Quality Systems Management

• Continual Process Improvement: ISO 9000, 2000
• Components of a Quality System: CTTI, 2010
Quality Systems Management

• Say What You Do
• Do What You Say
• Prove It
• Improve It

Reference: Janet Woodcock, MD  FDA Director of the Center for Drug Evaluation and Research ,  Developing Effective Quality Systems in Clinical Trials , CTTI: Oct 2010
Say What You Do
Say What You Do

• Collaboration by Research Management
• QA incorporated into Office of Human Research Protection (OHRP)
• Policies and Guidances
• Standardized Research Tools
• IRB, Contract, ICF Observation Reviews
Convened IRB Review:

• Panel Members
• Panel Minutes
• Approval/Acknowledgement Documents
Pre-Award Contract:

• Medicare Coverage Analysis (MCA)
• Center for Medicare & Medicaid Services (CMS) Determination for Device Trials
• Consistency between MCA, CMS & Budget
Pre-Award Contract....continued:

• Consistency between Contract, Protocol & Informed Consent

• Are all required signatures present
Say What You Do

Post-Award Contract:

• Consented Subjects in EMR
• Amendments Requiring Changes to Contract & Budget
• Verify Billing Charges
• EMR Status
Informed Consent Observation:

- Version
- Location
- Explanation
- Comprehension
- Documentation
Do What You Say
• Policies & Guidances
• Quarterly GCP Lectures
• IRB Newsletters
• Quarterly Research Forums Comprehension
• Intranet Resources
Prove It
Prove It

- VP Academics
- IRB Chair
- OHRP Manager
- Summary of Findings
- PI
- Study Staff
- QA Review
- Notification

Review Process
Prove It

Trend Analysis of Clinical Study Review:

• Delegation of Authority, Qualifications, Training
• General Regulatory
• Informed Consent
• Eligibility
Trend Analysis of Clinical Study Review ...cont:

• Adverse Events
• Compliance
• General Data Quality
• Test Article Accountability
Delegation of Authority Major:

- Non-study staff performing study procedures
- Incomplete DOA after trial open
- Per protocol, unqualified study staff performing study procedures
Delegation of Authority Minor:

• Expired Documentation of Staff Qualifications
• PI did not sign and date study staff tasks promptly
### Departments

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• GCP Education of High Risk Findings
• New Research Staff 60 day review
• Plan meetings with supervisors and managers
• Implementation of Contract/Billing Reviews
• Re-education
• Updating/Creating Policies/Guidance
• Yearly review of Policies/Guidances
Conclusions

- 4 steps to Quality Systems Management
- Changes to the Program to improve Quality
- Early Results are Promising
References

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• Quality Management in Clinical Trials, Pfizer
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