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Combining Research Quality and Compliance in a Community Hospital Setting

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Session Objectives

- Identify the relationship between quality, research and compliance in a community hospital setting
- Illustrate practical solutions to improve the budget and contract negotiation process
- Provide guidance for auditing the community hospital research program, with an emphasis on quality improvement.



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Community Hospital Challenges

- Small research departments
- Limited FTE's to administer the IRB
- Inexperienced Principal Investigators and clinical research staff
- Research function less structured than the academic setting, i.e., no support departments, established policies and procedures



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Initial Steps

- Moving from individual hospital IRB's to a central IRB
- Administrative support
- Board support
- Physician cooperation



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Advantages

- Establish an infra-structure to support research within the system
- Standardize policies and procedures to meet Federal regulations
- Allow investigators to apply for approval of protocols in a “central” location but conduct the study at all entities



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Continuing Steps

- Establish a Clinical Research Committee
- Develop policies and procedures
- Examine the budget and billing process
- Centralize research contract review and establish templates
- Standardize the informed consent process
- Educate IRB members, investigators and clinical research staff



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Budget Process

- Budget Worksheet key to the process
- Provides a consistent method for calculating the study budget prior to negotiating the contract
- Facilitates appropriate billing practices by identifying tests, procedures, medication, etc. which may be billed to the subject's private insurance, Medicare or the sponsor
- Involve Finance and Cost Accounting early in the development process



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Budget Worksheet

BUDGET WORKSHEET						
Name of study:						
Est. # of Subjects						
SECTION 1: ONE-TIME START UP FEES						
Study Activity	Activity Details		Total Number of Hours	Dollars per Hour	Projected Expense	Expected Revenue
Regulatory	Initial CHS CIRB preparation by Clinical Research Coordinator			\$80.00	\$0.00	
Budget/Contract	Budget/Contract Negotiation			\$80.00	\$0.00	
PI Administrative	PI Project Oversight			\$200.00	\$0.00	
Legal	Legal Review			\$375.00	\$0.00	
Site Administrative	Advertising Fee				\$0.00	
	Pharmacy Set Up Fee				\$0.00	
	Total One-Time Fees				\$0.00	
SECTION 2: STUDY CONDUCT FEES						
Study Activity	Activity Details	Number of hours per activity	Total Number of Hours	Dollars per Hour	Projected Expense	
Site Visits	A. Site Selection Visit					
	Sponsor/Investigator meeting	0	0	\$200.00	\$0.00	
	Sponsor/Clinical Staff Meeting	0	0	\$80.00	\$0.00	
	Time spent with monitor	0	0	\$80.00	\$0.00	
	Total Site Selection visit	0	0		\$0.00	
	B. Site Initiation Visit					
	Sponsor/Investigator meeting	0	0	\$200.00	\$0.00	
	Sponsor/Clinical Staff meeting	0	0	\$80.00	\$0.00	
	Preparation for site visit	0	0	\$80.00	\$0.00	
	Time spent with monitor	0	0	\$80.00	\$0.00	
	Total Site Initiation Visit	0	0		\$0.00	
	C. Interim Site Visits					
	Sponsor/Investigator Meeting	0	0	\$200.00	\$0.00	
	Sponsor/Clinical Staff Meeting	0	0	\$80.00	\$0.00	
	Preparation for site visit	0	0	\$80.00	\$0.00	
	Time spent with monitor	0	0	\$80.00	\$0.00	
	Total Interim Site Visits	0	0		\$0.00	



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Billing Process

- Involve Patient Accounts Department
- Develop forms to identify tests, etc., as research vs standard of care
- Educate staff
- Monitor!



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Patient Registration Worksheet

• PATIENT REGISTRATION/BILLING WORKSHEET

- Clinical Department Guarantier # _____
- Patient Name: _____
- Diagnosis: _____
- Clinical Trial: _____
- DOB: _____
- Phone#: _____
- Patient Account #: _____
- Insurance: _____
- Insurance Other: _____
- Diabetic: Yes _____ No _____
- Allergies: Yes _____ No _____ List Allergies: _____
- _____
- Trial Specific Tests: _____
- Required Date: _____
- Pt. Preferred Scheduling: _____
- Scheduled Date: _____ Time: _____
- Scheduler: _____
- Admitting Notified: Yes _____ No _____ Name: _____
- Patient Accounts: Yes _____ No _____ Name: _____
- Order Faxed: Yes _____ No _____ Department#: _____
- Additional Notes
- Reviewed By: _____ Date: _____



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Compliance and Quality Issues

- Develop streamlined contract review/approval mechanisms
- Ensure research billing is in compliance
- Auditing and Monitoring
- Why is quality of care important?
- Enforcement efforts via the False Claims Act



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Contract Review and Approval

- Develop contract review template with the input of outside counsel
- Provide education to staff involved in the review/negotiation process
- Provide outside counsel with template and reviewer's comments to aid in the expedited review of the contract



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Key Contract Provisions

- Indemnification
 - Often the most confusing aspect of the agreement
 - Beware of when the sponsor attempts to limit their liability only to claims/damages caused “directly” by the drug or device
- Compliance
 - Attach a copy of your Code of Conduct as an exhibit. Sponsor should agree to adhere to your compliance program
- Independent Contractor
 - It should be clear that this is not an employer-employee relationship



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Research Billing Compliance

- Cooperation between departments is essential
- Audit current procedures at least yearly
- Work with the billing department to assure monitors are in place (can be done quarterly)
- Update policies at least every 3 years; more frequently if laws and regulations change



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Why is the Compliance Office Involved?

- We are here to help you fulfill your roles and responsibilities in a manner that abides by our Code of Conduct
- We want to help ensure compliance with laws, regulations and your own policies and procedures
- We can help audit your department and help set up monitors for you



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Auditing versus Monitoring

- Auditing is an independent, objective process that evaluates a program or process. It is a more formal review that measures compliance with a particular set of internal or external standards. Auditing is generally performed by the compliance department or an external auditor
- Monitoring is a management tool that is used to provide ongoing quality assurance to mitigate risk. Reviews are repeated periodically during the normal course of business. Monitoring is generally done on the department level



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Research Auditing

- Informed Consent
- Billing
- Contracting



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Research Monitoring

- Quarterly
- Choose areas of potential risk
- Determine sample size
- Submit action plan if monitor shows areas of concern



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Why is Quality of Care Important?

- Government regulators have begun using the False Claims Act to target hospitals and nursing homes for providing poor quality of care or for providing unnecessary services
- In 1999, the Institute of Medicine published “To Err is Human: Building a Safer Health System”, which estimated up to 98,000 Americans die each year from medical mistakes
- Our government is now using its enforcement authority to drive quality of care in the name of patient safety
- The False Claims Act is the tool for enforcing quality of care



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False Claims Act and Research

- No cases to date specific to quality of care or billing for unnecessary services
- However, easily extended to research
 - Double billing
 - Billing for services that we promised to be gratis
 - Different levels of care
- Research fraud under a False Claims Act theory
 - Weill Medical Center paid 4.4 million to settle allegations of research grant fraud by improperly reporting and accounting for spending
 - Institute for Cancer Research agreed to pay 2.3 million to settle false claim accusations that they improperly used grant monies and submitted false reports



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Informed Consent

“Scientific progress is morally optional, while respect for human beings and their self determination is not.”



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Informed Consent

- First Sentence of the Nuremberg Code – “The voluntary consent of the human subject is absolutely essential.”
- Belmont Report – Respect for persons incorporates at least two ethical convictions: first, that individuals should be treated as autonomous agents, and second, that persons with diminished autonomy are entitled to protection.”



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Common Rule

- 45 CFR §46.116: "...The information that is given to the subject of the [legal] representative shall be in language understandable to the subject or representative..."



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Addressing Barriers

- Vulnerability
- Limited English Proficiency and Short Form Consent
- Low Literacy or Blind Subjects and oral presentation
- Deaf Subjects
- "Research Speak"



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Resources

- Jana L. Lacera: jlacera@comhs.org
- Nancy E. Moser: nlund-moser@comhs.org
- CHS CIRB Web Site: www.drcomhs.org
- Clinical Research policies and worksheets available upon request
- Clinical Trials Administrator; August 2007
- IRB Advisor; August 2007



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