



Community Hospital Research Programs: A Compliance Officer's Friend or Nightmare

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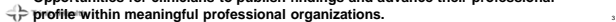


- Building a successful research program in a community hospital setting can be a disaster or a delight for a Compliance Officer depending on the level of collaboration in building/perfecting the model
- Often research was not on the Compliance Officer's radar until processes were already in place. But a collaborative approach to FDA/ OHRP Regulations, Research Billing, COI, Quality Controls, FMV, Stark and Sunshine Act concerns will yield best practices
- Operational models centralized vs decentralized: when to consider centralizing operations and regulatory oversight. Reporting metrics to assist compliance oversight



Understand Why Community Hospitals Participate in Clinical Research

- Participation in the advancement of science and enhancement of a clinician's understanding, diagnosis, treatment, and prevention of disease.
- Clinician / Scientist recruitment – attracting high quality care givers.
- Clinical trials give patients access to new medications and keep doctors attuned to the latest research and therapeutics.
- Generate additional revenue.
 - Attracts new patients – even patients who may not ultimately enroll may choose to continue their care at the hospital
 - Diversify revenue streams: New product lines, grants, subcontracts, Intellectual Property
 - Becoming a so-called "Center of Excellence"
 - Development of Philanthropic Strategy
- Advancement of a hospital or a system's mission.
- Marketing and enhancement of reputation, brand, perception – positive buzz and publicity.
- Opportunities for clinicians to publish findings and advance their professional profile within meaningful professional organizations.



Research at the Community Hospitals

- Often ancillary and therefore “under the radar” (based on interests of individual physicians)
- Administration and Compliance may not be aware of scope and volume of research program and efforts
- Research is Not highlighted the way clinical programs are and not integrated into overall operations (Oncology is typically the exception)
- Underpowered Research Infrastructure often has an IRB Human Subject Protection Foundation without focusing on Strong GCP and Clinical support
- Caution for non-employed Physicians and staff: Access to patients and records does not equal permission to engage in research

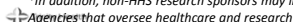


Know the Research Risk Primary Players and Their Responsibilities*

- **Department of Health and Human Services (DHHS)**
 - Office for Human Research Protections (OHRP)
 - Centers for Medicare and Medicaid Services (CMS)
 - National Institutes of Health (NIH)
 - Food and Drug Administration (FDA)
- **Office of the Inspector General (OIG)**
- **Office of Research Integrity (ORI)**
- **Office for Civil Rights (OCR)**

**Agencies that oversee research*

**In addition, non-HHS research sponsors may impose additional requirements, e.g. A, DOD, EPA.*



What do you need to Know – Research Office

- Historically Research focused primarily on IRB operations
- BUT Human Subject Protection Programs need to be familiar with ALL regulatory requirements: Research Billing, MCA's, HIPAA, COI, Contracts, FDA IND/IDE/Biologics/LDT's etc. (Is this possible?)
- A Strong relationship between Compliance Department is critical and must be cooperative
- The Compliance Department can be an ally in preventing, identifying, and correcting compliance concerns
- Symptoms of current Compliance Concerns/Problems can be seen through the eyes of the Research Office
- But, if the relationship and communication is not strong then Research can exacerbate these same conditions = Nightmare
- The key is to work together building on each other's strengths and identifying needs



What happens when you don't have the right people or training?



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Where can the Compliance Office Help

- Conflict of Interest Disclosure
- Fair Market Value determinations
- Stark Issues
- Physician Owned Distributor (POD)
- Consulting Agreements
- Billing Processes that cross department lines and responsibilities
- Research Billing Quality Audits
- Billing Denials and Reconciliation
- HIPAA/HITECH and BAA's

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Working With The Compliance Office

Often research was not on the Compliance Officer's radar until processes were already in place. But a collaborative approach to FDA/OHRP Regulations, Research Billing, COI, Quality Controls, FMV, Stark and Sunshine Act Concerns will yield best Practices

- Cross referencing information allows for better monitoring and Validation
- Collaborative Training Leads to greater understanding and reconciliation of SOP's that are perceived to be conflicting
- Selective monitoring/auditing reaffirms Quality and Compliance

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Overlapping Issues Offer Opportunities to Collaborate on SOP's

- Work with Compliance to develop SOP's that share identification and reporting of risks:
- Financial Relations and Conflict of Interest is tracked on a per study basis
 - Compare to annual reporting to compliance
 - Sanctions are reviewed per study
 - Compensation for Clinical Trials needs to be considered in Total Compensation
 - Watch out for overlapping consulting relationships with Sponsors and Clinical Trial Participation
 - Research Billing processes allow a peek into the quality of departmental processes
 - Non-Employed PI's Conducting Research on Site
 - Pay Hospital FMV for services, Submit to local Review/Oversight
 - Patient perception is that the Hospital is conducting the research



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Community Hospital Research Programs Desire Collaborative Relationships with Academic Medical Centers

How do these Collaborations impact the overall risk to the Community Hospital?



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Compare Academic Medical Center Research to Community Hospital Research Programs

- Planned and fully Integrated into the organizational mission
- Equal to other components of the mission
- Supported by Institutional or Departmental Budgets and Resources
- To add to the concerns of Compliance Offices there is an obvious incentive to collaborate with Academic Medical Centers
 - The AMC is typically the 600 lb. Gorilla in the relationship
 - Who is monitoring and under what SOP's
 - Should MCA's be compared to ensure agreement?
 - Patient has visits split between institutions – How is billing/reimbursement set up



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Compare Academic Medical Center Research to Community Hospital Research Programs

- **Most patients at AMC's have multiple medical problems that can complicate results, or have to be recruited with the promise of payment to participate in a study.**
- **Community hospitals, on the other hand, have a constant supply of patients who usually represent a good sampling of the general population.**
- **To serve these patients, several resources exist:**
- **Pharmaceutical Industry-Sponsored Clinical Trials**
 - Bio-tech organizations are always looking for sites to test new medications, or new indications for pre-approved medications. Many are ready made and fully funded
- **Health services (i.e., outcomes and quality) research**
 - Hospitals performance data can be used to develop and measure the effectiveness of new interventions or procedures including a clinicians program
- **Self-funded research**
- **Federally Funded/Foundation-funded/Grant Funded research**



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With Opportunity Comes Challenges and Risks

- **New data show number of principal investigators dropping 11% globally, and 20% in U.S. Centerwatch White Paper April 25, 2011**
 - Creates opportunity and need for Community PI's to engage in Research
- **But Community Hospitals have access to a wide range of conditions and diversity in patients**
- **Patient recruitment and retention can be challenging.**
- **Investigators compensation models often do not allow for significant time to be invested in research pursuits. Need to understand FMV when budgeting for Physician services**
- **Financial compensation (funding) may be too low.**
 - Hospitals and Investigators to be budget savvy –to understand the full costs of conducting research and demand adequate compensation. Where possible Centralize Research Finance
 - Feasibility assessments are necessary to avoid costly mistakes (Staffing costs, adverse sponsor relations, resources)
- **Compliance expectations on organizations supporting human subjects research are considerable (e.g., operational, regulatory, market, reputational risk).**
- **Geography issues if a community health system is spread over wide geographic areas with several outpatient facilities; can create challenges for billing and other operations.**



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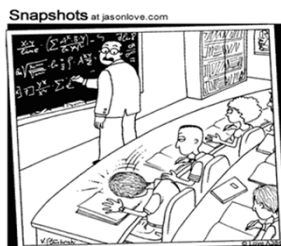
Participation in Clinical Research Challenges and Risks

- **Voluminous and ever changing regulations make clinical trials difficult to manage and oversee.**
 - Direct: FDA, OHRP NIH
 - Secondary: HIPAA/HITECH, Radiation Safety, Environmental Safety, Intellectual Property, Medicare billing
- **Conflict of Interest ("COI"): Balancing needs of patient with desire to spur enrollment in studies.**
- **Many physicians don't know or are not fully Trained on governing laws and regulations.**
 - FDA, OHRP, etc.
 - Research patient billing concerns
 - Potential False Claims Act violations (billing compliance)
 - Liability concerns
- **Potential increase in risk for medical malpractice (research monitoring makes this unlikely)**
- **Importance of indemnification in contract negotiation**
- **Ethical consideration including concern for Institutional Mission (Faith Based CH)**
- **Stark/Anti-kickback**
 - Financial disclosure may deter participation by physicians
- **Physician Payments Sunshine provision embedded within Section 6002 of the Patient Protection and Affordable Care Act (PPACA).**
- **Potential concerns within the community about engaging in sensitive research (i.e. Stem Cells, Gene Therapy, Emergency Research, Animal Research, etc.).**



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Sound Easy so Far?



Professor Herman stopped when he heard that unmistakable thud - another brain had imploded.

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Identify Risks and Solutions by Area of Concern

Physicians

- Are physicians (or others) engaged in research without you knowing
 - Are they appropriately vetted and credentialed
- Is PI initiated research being initiated without adequate training or resources
- Innovative Practice of Medicine vs Research
- What if a physician has privileges at both institutions and wants to conduct his study at both sites - can he use an investigational product at both sites - PI Initiated studies
- Understand the difference between Employed Physicians and Physicians with Privileges
- What if you have a nurse or other staff going for a PhD at a local Medical Center and is conducting research at your CH to submit as part of her degree

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Identify Risks and Solutions by Area of Concern

Research Billing

- Do you have a process for determining whether the study is a Qualifying Clinical Trial
- Do you have an MCA process to ensure appropriate billing for research vs routine care
- Does your institution have a system for identifying and flagging Research Patients
- Do you have a "hold" process to prevent inappropriate billing
- Do you have a QA process to reconcile billing before bills are released
- Does Compliance work with you to audit your processes or MCA determinations to ensure your procedures are correct and strictly adhered to
- Are your study budgets and physician payments in line with FMV

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Identify Risks and Solutions by Area of Concern

- Do your investigators have who have significant conflicts of interest
- How do you Review monitor and Manage Conflicts of Interest
- Do You Review and Monitor Institutional Conflicts of Interest
- Is your IRB Adequately Staffed and Trained
- Is Your IRB Conflicted (Use Researchers as IRB members)
- Are you ignoring potential Intellectual Property interests



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Assessment Your Areas of Risk: Who is doing What and Where?

- Many community hospitals are hosts to research without knowing it.
- Physicians may be signing Clinical Trial Agreements without hospital's involvement with the intention of performing most services in their private practice office.
- Once services associated with a clinical trial necessitate use of hospital resources (i.e., nurses, equipment, space), the hospital must be involved.
 - Even if only Standard of Care services are involved in the trial's tests and procedures, there are responsibilities that need to be met
- Many organizations have developed policies that dictate the importance and requirements for clinicians to engage the hospital when/if its facilities may become necessary to execute the provisions of a clinical research protocol.
 - Research feasibility.
 - Credentialing issues.
 - Copy of IRB approval letter.
 - Identification of each research participant.
 - Contract that details payment for non-Standard of Care items and services.
 - Documentation that Medicare intermediary has provided approval, as necessary.



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Assessment Your Areas of Risk

Assessment of the current state is crucial. The follow steps may help determine what is going on but make sure you work with compliance in this assessment:

1. Interview departmental administrative leads and ask for any research-related records and/or supplies
2. Interview nurses, pharmacy, and lab leads to determine if any clinician has requested research related services or special billing procedures
3. Determine if investigational products are entering your Pharmacy and/or the OR
4. Review IRB Financial to identify instances where a disclosure was made for the purposes of a research study but not present in annual reporting
5. Review policy manual with Compliance to assess for scope of research-related policies to address significant risk areas
6. Obligate all non-employed Physicians to disclose what if any research they are conducting
7. Any use of Hospital Facilities or equipment must be referred to the Research Office



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Assessment cont.

Proactive Monitoring:

- 8. Need for a signed informed consent document and consistency between Protocol, Clinical Trial Agreement and Consent.
- 9. Ensure that Research conducted on site have site IRB Approval or are under Authorization Agreement
- 10. Search PubMed for Publications involving your site or Investigators
- 11. Medical Records belong to the Hospital and any request for research use should be referred to the IRB
- 12. Identify any Grant funds that are being used for research
- 13. Talk to Payroll and determine if any professional staff are having a portion of their salaries paid by Grant funds.
- 14. Check clinicaltrials.gov and grants.gov to determine if your site has been listed as a research site for any active studies.

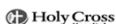
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to assist Compliance Oversight



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Holy Cross Hospital Regulatory Model

- ✓ Experienced/Certified CRAs to ensure Clinical and Data Quality
- ✓ Central IRB Model to serve HCH and Affiliate Physicians with Local Oversight
- ✓ Central Research Pharmacy Management
- ✓ Central Regulatory and QA Model
- ✓ Risk-based Data Monitoring
- ✓ Close coordination with Compliance Office
- ✓ Expedited Contract Process (CDA, CTA, MTA)



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Holy Cross Hospital Operational Model

- Electronic SOP review system (PolicyStat) that allows for collaborative review and input – Compliance, Finance, Nursing etc. Included in Research Review
- Research Billing Committee – Cross Departmental (Hospital Billing, Medical Group Billing, Registration, Insurance Verification etc.) discuss denials, process issues and improvements
- Research Oversight Committee – Discuss Strategic Planning, Compliance, Support Concerns, Achievements, Finances etc.
- Steering Committees – Ongoing study recruitment, New Study Feasibility, Staffing, Publications, Marketing etc.



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Holy Cross Hospital Operational Model

- Electronic Contract Review for CTA's
 - Checklist for COI, Sanctions, Version Tracking, FDA,
 - ICF Protocol CTA Check for Consistency
- Centralized Monitoring/Auditing and Education
- Centralized Research Finance
 - MCA review and approval
 - Budgeting
 - Billing Reconciliation
- Centralized CRA Staffing QA model



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What If Scenario's

(Handouts of Scenarios to be provided at Session)
Interactive Discussion



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