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Integrating Community Hospital Based Research in a System Wide Network: Just Mix in Compliance, Collaboration, Billing, HIPAA, Central IRB then Stir Until Done

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High Level Summary

- Assess What you Have in Place
- Build Slowly – with an Eye on Compliance and Standardization
- Envision Your Final Design Model

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High Level Summary

- Clinical Research on a Multi-site/Multi-state scale is not a Compliance Officers favorite undertaking, irrespective of financial and staffing resources available. Build an expert team with Collaboration and Communication as central themes.
- Integrating a successful Community Hospital Model across an entire Healthcare Network Requires New Workflows and New Challenges to overcome – Move Slowly But Decisively
- Operational models centralized vs decentralized: when to consider centralizing operations and regulatory oversight and what needs to remain decentralized? Establishing Compliance Oversight and Metrics

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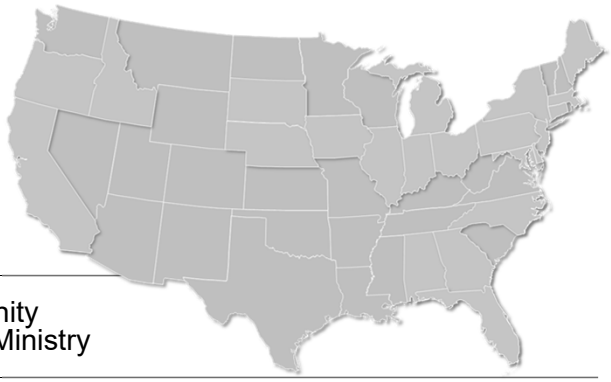
Trinity Health's 22-state diversified system today



$18.3B In Revenue

1.5M Attributed Lives

$1.1B Community Benefit Ministry

133K Colleagues

7.8K Employed Physicians & Clinicians

28K Affiliated Physicians

94 Hospitals* in 22 states

18 Clinically Integrated Networks

17 PACE Center Locations

109 Continuing Care Locations

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*Owned, managed or in JOAs or JVs.

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Research in Trinity Health

Research conducted at approximately 1/3 to 1/2 of the hospitals

- Test articles (drugs, devices, biologics)
- Investigator initiated
- Residents / Fellows

- 26 IRBs / System Research Office

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First Understand Why Community Hospitals Participate in Clinical Research

- **Participation in the advancement of science and enhancement of a clinicians understanding, diagnosis, treatment, and prevention of disease.**
- **Clinician / Scientist recruitment – Attracting High Quality Caregivers and Researchers.**
- **Clinical trials give patients <u>access</u> to new medications and Creates Opportunities to Expand Local Collaboration for the latest Research and Therapeutics.**
- **Generate <u>additional revenue</u>.**
  - Attracts new patients – even if patients ultimately choose to continue their standard care
  - Diversify revenue streams: New product lines, grants, subcontracts, Intellectual Property
  - Establish a “Center of Excellence”
  - Development of Philanthropic Strategy
- **Marketing - enhancement of reputation, brand, perception – positive buzz and publicity.**
- **Opportunities for clinicians to publish findings and advance their professional profile**

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Why do Healthcare Systems Desire Collaborative Models

- Richness of data
  - Opportunity to Identify Best Practices
- Attract Pharma studies
  - Access to Cutting Edge Clinical Trials
- Standardize Operations and Identify Best Practices
  - Efficiency, Compliance, Safety
- Attract High Quality Physicians
- Encourage Cutting Edge Innovation
  - Innovation Funding Program

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Research Across Multiple Community Hospitals
Need to Understand the Concerns of a Compliance Officer

- Considerable Variety of Size, Scope and Complexity of Research
- Employed Vs Non-Employed Physicians exist within same system
  - Caution for non-employed Physicians and staff: Access to patients and records does not equal permission to engage in research
- Often Research is 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 focus on Strong GCP and Clinical support

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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. VA, DOD, EPA. Agencies that oversee healthcare and research*

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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 (CTA's, CDA's, MTA's, Physician Contracts etc) FDA IND/IDE/Biologics/LDT's etc. (Enormous Burden from a System Perspective and on a Central IRB)
- Multiply Those Concerns Times the Number of Collaborating Sites
  - A Strong relationship between Compliance Department is critical and must be cooperative
- The System Compliance Office Must be an Ally in designing systems to prevent, identify, and correct potential compliance concerns – Identify and Promote Best Practices
- Collaboration: Symptoms of current Compliance Concerns/Problems can be seen through the eyes of the Local Research Office
- But, if the Cooperation and Communication are not strong then Research can Exacerbate these same Weaknesses = Nightmare - Secondary use of data/samples – PI initiated IND/IDE, Research Billing, COI
- The key is to work together building on each other's strengths and identifying needs

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What happens When you Don't Have the Right People or Training?

Standardization

Quality Assurance

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Where can the Compliance Office Help

Policies Standardized Through System Office

- 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
- Sunshine Act Tracking and Monitoring

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Working With The Compliance Office on a System Level

Having A Standardized Approach to General Compliance Establishes a Platform for Developing a Research Compliance Model. Consequently 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 and Standardizing Processes Allows for better Monitoring and Validation
- Collaborative Training Model 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 Concerns Offer Opportunities to Collaborate on SOP's

Develop SOP's that share Responsibility for Identification and Reporting of risks:

- Financial Relations and Conflict of Interest is tracked on a per study basis
  - Compare to annual COI reporting to compliance
  - Sanctions are reviewed per study based on System-wide tracking System
- Compensation for Clinical Trials needs to be Considered From FMV Perspective
  - Local Compliance Reports up to System Office for Quality and Compliance
- Watch out for Overlapping Consulting Relationships with Drug/Device Suppliers and Clinical Trial Participation
- Research Billing Processes Allow a Peek into the Quality of Departmental Billing Processes – Identify Weakness Before Entering into System-wide Endeavors
- 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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Participation in Clinical Research Challenges and Risks

- **Physicians Unfamiliar with Voluminous and ever changing regulations**
  - 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.**
- **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 Hospital System)**
- **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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Need to Assess every Site for Basic Compliance and Training Issues

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Assessment Your Areas of Risk: Engagement in Research

- **Many Community Hospitals are Hosting Physicians Who Are Engaged in Research**
- **Physicians may be signing Clinical Trial Agreements without hospital's involvement with the intention of performing most services in their private practice office.**
- **Once Research procedures associated with a clinical trial involve use of hospital resources (i.e., nurses, equipment, space), the Hospital Research must be involved.**
- **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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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 Conflict of Interest

- Do your investigators have significant conflicts of interest (PODS?)
- How do you Review monitor and Manage Conflicts of Interest
- Do You Review and Monitor Institutional Conflicts of Interest
- Review IRB Submitted Financials to identify disclosure made that Have Not been Submitted to in Annual Reporting

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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. Mandate non-employed Physicians disclose any research they are conducting
6. Any Use of Hospital Facilities, equipment or Medical Records must be referred to the Research Office
7. Need for a signed informed consent document and consistency between Protocol, Clinical Trial Agreement and Consent.

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Assessment cont.

Proactive Monitoring:

8. Is your IRB Adequately Staffed and Trained
9. Is Community IRB Conflicted (Use Researchers as IRB members)
10. Are you Monitoring potential Intellectual Property interests
11. Search PubMed for Publications involving your site or Investigators
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 to determine if your site has been listed as a research site for any active studies.

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Moving Toward Consolidation:

From Multisite Research Program to a Coordinated Research Network

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Opportunities…..

- Moving to Epic creates an opportunity to consolidate / collaborate finance model/ business office work, contracts, etc.
- Leverage Expertise to Create Oversight Based on Experience within Research Disciplines in Addition to Experience in Complex Multi-site Compliance Models
  - Identify Your Subject Matter Experts
- Begin By Building Research Collaborations at the Data Sharing Level First Before Moving to Multi-site Interventional Clinical Trials and/or PI Initiated Studies

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Moving to A Single, Integrated Platform

Trinity Health is moving to one instance of Epic

- ✓ People-centered care experiences
- ✓ Seamless integration among colleagues and clinicians
- ✓ Operational excellence across the entire care continuum (acute, post acute, physician offices)

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The Challenge to Move to the Next Level

- Building a Large Scale Research Program Based on the Collective Experience of Community Hospital Based Programs can be an Enormous Challenge for a Health System depending on the level of Collaboration, Coordination, Training and Oversight Established in building/perfecting the model
- By Building a Strong Foundation for Research Based on Centralized SOP's, Data Sharing and Shared Repository Model allows for Growth to More Complex Research
- Operational and Compliance models can be centralized or decentralized:
  - When to consider centralizing operations and regulatory oversight.
  - Develop Reporting metrics to assist Compliance Oversight
- Beyond SOP's: Harmonizing Multi-site Research Procedures, Monitoring and Compliance is an Enormous Challenge (Just ask OHRP, FDA OCR etc.) But a collaborative approach to FDA/ OHRP Regulations, Research Billing, COI, Quality Controls, FMV, Stark and Sunshine Act concerns will yield best practices

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Trinity Health: Start by Leveraging Existing System Strengths and Infrastructure

- Central Corporate Research Office
- Central Research Compliance Model
- Central IRB for Multi-center Data Outcomes Studies
- Strategic Assessment of All Sites
  - Scope of Research Programs
  - Quality and Compliance Assessment
- Regular Strategic, Operational and Educational Meetings
- System Wide Innovation Program and Support

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Operational models centralized vs decentralized: when to consider Centralizing operations and regulatory oversight. Reporting metrics 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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Envision a New Model for Multi-site Clinical Trials

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What If You Had The Opportunity to Establish a New Clinical Trials Model

- How would you challenge the status quo?
- What would you seek to streamline?
- What steps would you take to avoid/eliminate redundancies and potential bottlenecks?
- How would you build consensus and trust?
- What would be the impact?

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Objectives

1. Improve the speed, efficiency, design, and launch of clinical trials (Measure Start-up Times)
2. Facilitate scientific innovation (Have resources for Developing IP)
3. Improve the selection, prioritization, and completion of clinical trials (Measure Accruals/Time, Effort, Screen failures,)
4. Foster expanded participation of both patients and physicians

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Communication Plan

Network Sites

Regulatory Affairs

FDA

cIRB

Industry Sponsors

e-Portal

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Operating Model for Collaboration

- ✓ Master Clinical Trial Agreements & Work Orders
- ✓ Reliance Agreement for Central IRB
- ✓ Single Study Budget and Grant Sub-Awards
- ✓ Integrated Informatics Platform (e.g., EDC, CTMS)
- ✓ Risk-based Data Monitoring & Central DSMB
- ✓ Central Lab for Molecular Analysis (Where Necessary to Ensure Consistent Results)
- ✓ Front Door Repository Protocols for Tissue Procurement & Banking
- ✓ Metrics to Assess, Refine, & Support Decisions
- ✓ Designated Site-based Liaison as Primary Contact

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Contracting Needs

1. Memo of Understanding Agreement for cIRB Reliance
2. Master Clinical Trial Agreement and Sub-Awards
3. Study-Specific Work Orders
4. Physician Agreements Where Necessary

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Single Central IRB Reliance

- Network Institutions Given "*seat at the table*"
- Build on Existing IRB Collaborative Model or Outsource?
- MUST BE:
  - AAHRPP Accredited
  - Web-based Communication Platform
  - Commitment to Optimize Efficiencies and Reduce Redundancies
- Possible Back-Office Model using Commercial IRB
- Consider Just in Time Start-up Model

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Evaluating Site Feasibility and Selection

1. **Assessment of:**

- Local Study Interest
- Site Resource, Capabilities & Accrual
- Estimated Study Budget

2. **Followed by:**

- Formal Negotiation of Contract with Industry
- Study-Specific Work Order
- Detailed Budget and Billing Schedule

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Budgets and Grants

- One-Size-Fits-Most" Trial Budgets based on Discipline (Where Possible)
- Local Support to Ensure Real-time Communications Through Local Liaison

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Risk-Based Data Monitoring

Efficient and Effective Site Monitoring to Reduce Time and Cost *without* Compromising Data Integrity

- Subject Eligibility Confirmed at Enrollment
- CRFs Collecting Only those Data Elements Necessary to Support Study Endpoints
- Targeted Source Data Verification (SDV) of Key Data Elements
- Well-Trained Site and CRA Staff

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Impact of a Solutions-Driven Model

- Time Savings
- Cost Savings
- Value Added Services and Financial Resources Enhance Incentives for Collaboration
- Satisfaction that comes with Knowledge that You are Making a Difference for All Patients

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Process Design Goals

- Faster
- Easier (easier for most – never more complicated)
- Centralized to reduce effort – avoid duplication
- Collaborative – to share success
- Open Access – to ensure transparency
- Supportive – to ensure success for all

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Questions

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