Starting at Ground Zero:
Assessment of Research Compliance at a Large, Community-Based Healthcare System

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Sharing Our Story:

Commitment
• How a newly integrated, multi-state, community based healthcare system has made the commitment to support research compliance system wide

Development
• Creating a research compliance assessment strategy that included both corporate and community hospital-based research compliance components

Implementation
• Challenges for a comprehensive research compliance program in an ever changing, complex healthcare environment
Agenda

- Who is Trinity Health?
- Beginning Steps
- Needs Assessment
- Structural Changes
- Implementation Plan
- Current State
- Future Challenges

Who is Trinity Health?
Our 21-State Diversified Network

- 1.7% of all babies in America are delivered at Trinity Health facilities
- 23,900 Affiliated Physicians
- 3,900 Employed Physicians
- 90 Hospitals* in 21 Regional Health Ministries**
- 49 Home Care & Hospice Locations Serving 116 Counties

Trinity Health’s Research Enterprise

- 25 local Institutional Review Boards (IRBs) in existence
  - Broad range of scope and size
  - Community hospital based
  - Academic medical center with university-based IRB
  - Numerous partnerships with external organizations

- Historically decentralized, locally driven operational model

- Greater emphasis on sharing best practices and standard work flows
Beginning Steps

Background Information

• Merger between Trinity Health and Catholic Healthcare East completed in 2013
• Created second largest not-for-profit health system in the U.S.
• Trinity Health’s inaugural Chief Academic Officer hired in 2012
  • The “Office of Academic Affairs” created with responsibility for Research, Graduate Medical Education (GME) and Continuing Medical Education (CME)
An Initial Commitment

• Director of GME hired 2013
• Director of Research position created in 2014
  • Responsibility for the leadership and direction of Trinity Health’s system wide research program
  • Serves as a liaison for research leaders across the system
  • Provides consultative services on operational issues (i.e., research administration, grants management, program planning)

Building a Foundation of Trust

• Developing relationships with research leaders
• Creating value
  • Monthly calls for Research Operational leaders
  • Monthly calls for IRB leaders
  • Committee structure:
    - Scientific Review Committee
    - Research Compliance Committee
• System level research support for Investigators
  • Who needs what
  • Data analytics challenges
  • System level research approval process
Research Compliance – A Gap

• Focused on advancing research operational best practices
• No formal role or structure to support research compliance ministry needs
  • FDA audit findings
  • Warning letters
• In 2015, senior management from both clinical and compliance teams agreed to jointly support a comprehensive research compliance assessment

Needs Assessment
How Big is the Gap?

• Contracted with outside experts to conduct a comprehensive assessment of research compliance infrastructure and resources at the corporate office and ministry locations
• On site visits with corporate staff and select ministry locations (October – December 2015)
• Phone interviews and survey administration at all sites

High Priority Recommendations

• Development of a system-wide research compliance (RC) program with adequate resources and expertise
  • 2 FTEs: Research Compliance Officer, Research Compliance Specialist
  • Establish charter for RC program
• Establish governance that separates RC from business and operational functions of the research enterprise
• Establishment of high level model policies and procedures
• Centralization of RC education and training
High Priority Recommendations

- RC program to create and maintain effective lines of communication
  - RCO the primary contact for IRBs within Trinity
  - RCO facilitate monthly IRB leader calls
  - RCO chair Research Compliance Committee
- Establish written standards of research conduct
  - Develop a “research supplement” to Trinity Health’s “Code of Conduct”

High Priority Recommendations (cont’d)

- RC program use audits and other risk evaluation techniques to monitor compliance and identify problem areas
  - Annual research compliance risk assessment process
  - Creation of system-wide auditing and monitoring team
- RC program initiate a model research billing program
  - Policies, procedures, templates
  - Explore ways to perform Medicare Coverage Analysis (MCA) for entities
  - Evaluate Clinical Trials Management System (CTMS) to help drive compliant billing practices
Formal Roles Developed

• Two Positions designated within Integrity & Audit Services department
  • Director, Research Integrity & Compliance
    - Leader of monthly IRB calls
    - Chair of Research Compliance Committee
    - Primary contact for IRBs within the system
  • Research Compliance Specialist
Transition Plan for Ministry IRB Leaders

• Communication plan for:
  • Release of recommendations and final report
  • Introduction of new RC roles and responsibilities
  • Consistent messaging in support of strategic plan

• Orientation planning for “hand-off”:
  • Individual orientation phone calls with new RC Director and existing Operational Research Director
  • Incorporation of annual risk assessment questions with orientation phone call

Key Considerations

• Consistent messaging on the differences between operational and compliance support
• Strong partnership between the compliance and clinical teams
• Recognition of the practical constraints faced by our ministries
  • Small programs with limited resources
  • Dual responsibilities covering both operations and compliance at some sites
Implementation Plan

Implementation of Research Compliance Workplan

- Leadership & Oversight
- Code of Conduct
- Enforcement & Discipline
- Education & Training
- Response & Prevention
- Risk Assessment
- Reporting Systems
- Auditing & Monitoring

Research Compliance Program
“Stub Year” Research Compliance Workplan

Research Compliance Organizational Chart

SVP Integrity & Audit Services
Corporate Compliance Officer
Institutional Official, System IRB of Record

Leadership & Oversight

Integrity & Compliance

HIPAA / Privacy Compliance

Audit Services (Finance)

Research Integrity & Compliance
Building the Team and Foundation

• Designation of Director, Research Integrity & Compliance (January 2016)
• Onboarding of Research Compliance Specialist (July 2016)
  • Transition from Hospital Integrity & Compliance auditing team
• Research Compliance Committee
  • Update and finalize charter, membership expansion
• Orientation to IRB local leaders
• Policies & Procedures

Education & Training

• Education
  • Access to industry newsletters
• Training
  • 2nd Annual Trinity Health Research Summit (Virtual)
    - Educational sessions by OHRP
    - Presentations – physician/clinician and resident tracks
  • Standardization to 1 online educational tool
• Communication
  • Internal websites
  • External / Public websites
  • Monthly IRB leader meetings
Risk Assessment for FY17 Workplan

- Workplan period mirrors Trinity Health financial year (July – June)
- Annual risk assessment & planning period (February – May)
  - Top down/Bottom up approach, engaging RHM and System Office stakeholders
- Integrated into IRB leader orientation calls
- Piggybacked onto findings of outside consultants’ report
  - “What keeps you up at night from a research integrity & compliance perspective?”
  - “What is the highest priority for support in FY17?”

1-800 Call Research Integrity & Compliance

Putting out the fires....

- FDA letters
  - Support in completing corrective action plans
  - Preparation for next on-site review
- Restart of research and IRB office at an entity
- Integration of new entities with research offices and IRBs
- Billing and privacy questions
Next Steps

Implementation of Research Compliance Workplan

- Leadership & Oversight
- Code of Conduct
- Research Compliance Program
- Education & Training
- Risk Assessment
- Auditing & Monitoring
- Reporting Systems
- Response & Prevention
- Enforcement & Discipline
Oversight, Code of Conduct, Response & Prevention

- Ongoing work with policies & procedures
  - Research Compliance Program
  - IRB of Record
- Supplement to the Trinity Health Code of Conduct
- Incident Management / Hotline / Reporting systems
  - Utilization of Trinity Health hotline, incident management tool and other reporting systems for research integrity & compliance

Auditing / Monitoring

- Model research billing program compliance guidance
- Risk Assessment design / development for next fiscal year
- Auditing & monitoring:
  - Local IRB auditing / monitoring plans
  - Local IRB policies / procedures
  - Finance, budgets
  - Privacy / Security
Response & Prevention
Enforcement & Discipline
• Financial Conflicts of Interest in research
  • Integration and standardization into System Office processes, tools
• Privacy compliance
• Response to FDA, other investigators; findings from audits requiring payback/adjustment
  • 60 day repayment rule impact

Future Challenges
Transition of IRB of Record

- RFP, interviews and selection in 2015
- Approval of selection by executive clinical leaders (January 2016)
- Transition workplan design & development (Spring 2016)
  - Transition of individual entity IRB service agreements from old to new IRB of record
    - Indemnification / Insurance
  - Service agreement between Trinity Health corporate and new IRB of record
    - Scope of work and staging of rollout (e.g., studies using data from 3+ RHMs; retrospective and/or prospective)
    - Membership on Scientific Oversight Committee; Research Compliance Committee
- Formal announcement scheduled July 2017

Organic Growth and Expansion vs Bandwidth

Changing healthcare environment from FFS to value-based
Budget, FTE constraints
Why research?

New entities joining Trinity Health with varied research programs
Expansion of research into non-acute (SNF, IRF, community health, population health)
Tools of tomorrow (FitBit story)
Data analytics
NCI “Cancer Moonshot”
The Future is Here

Provide efficient, value-added services

Questions
What questions do you have?

Contact Information

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