Tips and Tools to Develop a Research Compliance Program at Your Organization

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Agenda

• Research Compliance Environment
• Carolinas HealthCare System Overview, Compliance Program Structure, Research Program Statistics
• Developing & Implementing a Research Compliance Program  
  – Identifying the Need  
  – Expectations for Research Compliance  
  – Compliance Program Plan  
  – Stakeholders  
  – Implementation Plan
• Plan for Auditing & Monitoring the Research Compliance Program
• Physician Education Component for Research Compliance
• IRB Compliance
• Concluding Remarks & Questions
Compliance Programs Should Be In Place for All Research Entities No Matter How Big or How Small the Research Efforts.

Introduction

• Research Is Different for Universities, Hospitals, and Private Practices
  
  • However many of the components are the same
  
  • Today’s presentation will provide you with some basics to take back to implement your own program
  
  • Actual accounts of what can work and mistakes that have been made
Environment

Who expects compliance in Research?

- FDA
- OIG
- Sponsors
- Human Subjects
- Families of Subjects
- Institutions

Before implementing a Research Compliance Program, identify the compliance risks specific to the organization. Recruit key stakeholders to help implement the organization’s compliance plan of action for research.
Carolinas HealthCare System

- Largest health care system in the southeast
- Owns, manages or leases 23 hospitals
- Employs over 1,100 physicians and mid-level providers and more than 35,000 full-time employees in over 150 facilities throughout North and South Carolina

Corporate Compliance Department
Regional Oversight
The CHS Compliance Program

<table>
<thead>
<tr>
<th>Acute Care Facilities</th>
<th>Long Term Care Facilities</th>
<th>Other Entities</th>
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<tbody>
<tr>
<td>Anson Community Hospital</td>
<td>Cleveland Pines Nursing Center</td>
<td>Ambulatory Clinics</td>
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<tr>
<td>Carolinas Rehabilitation</td>
<td>College Pines</td>
<td>College of Health Sciences</td>
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<tr>
<td>Cleveland Regional Medical Center</td>
<td>Crawley Memorial Hospital</td>
<td>Corporate Operations</td>
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<tr>
<td>CMC</td>
<td>Ellen Sagar Nursing Home</td>
<td>MEDIC</td>
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<td>CMC-Lincoln</td>
<td>Grace Heights</td>
<td>Medical Education</td>
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<tr>
<td>CMC-Mercy</td>
<td>Grace Ridge</td>
<td>(100+ Faculty Physicians)</td>
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<td>CMC-NorthEast</td>
<td>Huntersville Oaks</td>
<td>Public Health</td>
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<td>CMC-Pineville</td>
<td>Jesse Helms Nursing Center</td>
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<tr>
<td>CMC-Randolph</td>
<td>Kings Mountain LTC Hospital</td>
<td>Research</td>
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<td>CMC-Union</td>
<td>Lillie Bennett Nursing Center</td>
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<tr>
<td>CMC-University</td>
<td>Sardis Oaks</td>
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<tr>
<td>Columbus Regional Healthcare</td>
<td>Wilkes Regional SNF</td>
<td>CPN &amp; NorthEast Physician Network</td>
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<tr>
<td>System</td>
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<tr>
<td>Grace Hospital</td>
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<td>Kings Mountain Hospital</td>
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<td>Roper St. Francis Healthcare</td>
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<td>Valdese Hospital</td>
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<tr>
<td>Wallace Thomson Hospital</td>
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<tr>
<td>Wilkes Regional Medical Center</td>
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The Corporate Compliance Program provides on-going auditing & monitoring in all areas of the Carolinas HealthCare System.

Board Level Support for Compliance

- The mission of the Carolinas HealthCare System is to create and operate a comprehensive system to provide health care and related services, including education and research opportunities, for the benefit of the people it serves.
- The three main components of the System’s mission statement are:
  - Healthcare and related services
  - Education
  - Research
- The Chief Compliance Officer updates the Board quarterly on the status of compliance and they maintain a high level of interest in the Research Compliance program.
Defining Our Culture

**Compliance**
- Knowing the Rules
- Following the Rules as they have been provided to you.

**Ethics**
- Understanding the Difference Between Right and Wrong
- Choosing to do the Right Thing.

**Integrity**
- Consistently doing the right thing, even when no one is looking.

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**Compliance Program Oversight of High Risk Areas**

- Overall Compliance Program Includes the Following Identified High Risk Areas:
  - Ambulance Services
  - Ambulatory Care
  - Behavioral Health
  - Cardiac Cath
  - Chargemasters
  - Clinical Care Management
  - Emergency Medicine
  - Health Information Management
  - Home Care
  - Human Resources
  - Laboratory
  - Material Resource Management
  - Medicare/Medicaid Cost Report
  - Medical Staff Services
  - Patient Accounting
  - Pharmacy
  - Radiology
  - Rehab Services
  - **Research**
  - Safety Environmental
  - Taxes
Carolinas HealthCare System
Clinical Research Program

- 700+ Open Clinical Trials
- 210 Principal Investigators
- Number of sites
  - 16 Hospital Locations
  - 5 Physician Practice Groups spanning various specialties (i.e. cardiology, urology, pediatrics, oncology, etc.)
  - Faculty and Resident Research
  - Dickson Institute
- Clinical Research Office
  - Local IRB
  - Contract Review
  - Regulatory Compliance Guidance (FDA, NIH, etc.)
- In-house Legal Department (Contract review and approval)

Identifying the Need for a Research Compliance Program

Four years ago …

- Decentralized
  - Standard Operating Procedures in place but not universally utilized
  - Clinical trial accounting decentralized (by practice or location)

- Inconsistent
  - Practice Managers, Research Managers, and Research Coordinators lacked communication
  - Coding and documentation guidance not disseminated universally
  - Compliance program sporadically applied

- Minimal Leadership Oversight
  - Clinical research office “fought fires”
  - Research Administration did not oversee all research
  - Organization leaders knew little about Clinical Research and its benefit to the organization
Developing the Research Compliance Program

- Model the research compliance program after the structure of a program that is currently in place and working
  - Compliance Matrix Model
  - Action Plan tool
  - Meeting requirements
  - Quarterly self-assessments
  - Regular education
  - Annual year-end testing of compliance program effectiveness
- Understand minor modifications may be necessary to successfully implement a Research Compliance Program

The Compliance Matrix Model (In place and working)

Chief Compliance Officer

Corporate Compliance Department

Facility Compliance Director (FCD) "Facility Compliance Leadership"
- Guides and enforces the compliance program in a Facility-level oversight role.
- Reports directly to Corporate Compliance Department.

Facility Compliance Advisor (FCA) "Facility Technical Leadership"
- Ensures expectations of corporate action plan have been fulfilled at the facility level.
- Reports to Facility Compliance Leadership.

Functional Compliance Coordinator (FCC) "Corporate Technical Leadership"
- Prepare corporate action plan templates for facility technical leadership.
- Functional risk area knowledge experts and resource for facility technical leadership.
Compliance Matrix Model for Clinical Research

• Clinical Research – unique risk area to the CHS Compliance Program
  – Result: Develop a similar, but separate structure for the research risk area

• Designate a Risk Area Expert *(Functional Compliance Coordinator)*
  – Director of Clinical Research Office

• Appoint Compliance Department Liaison
  – Dedicated to work with risk area expert and communicate Compliance Department expectations

• Research Matrix Representatives *(Facility Compliance Advisors)* identified by Research Administration and Corporate Compliance
  – Direct relationship to clinical research (i.e. sites conducting clinical research)
  – Those sites providing support to clinical research activities (i.e. lab, imaging)

Identify and Recruit Key Stakeholders to Develop and Implement the Research Compliance Program

• Chief Compliance Officer and Compliance Department
• Vice President of Research (or Research leader for the organization)

• Representatives from:
  – Clinical Research Office
  – Grants & Contracts Department
  – All hospital departments conducting research (or responsible party for the oversight of hospital departments conducting research)
  – Physician Practices (Practice Managers)
  – Laboratory
  – Medical Records
  – Patient Financial Services
  – Pharmacy
  – Information Services
  – Radiology
Action Plan Development and Implementation Timeline

Year 1:
- Kick-off Meeting
- Brainstorming session for Action Plan development
- Creation of basic compliance assessment

Year 2:
- Ongoing monitoring & auditing
- Preliminary Action Plan Implementation

Year 3:
- Revision of Action Plan based on annual effectiveness assessment and compliance advisor feedback
Action Plan Development – Year 1 and 2

Preliminary action plan focused on basic elements of an effective program

- Meeting expectations
- Conflict of Interest Disclosure expectations
- NIH grant recipient compliance
- Dissemination of research regulation and education information
- Site self-assessments (Compliance)
- Education of all individuals responsible for research
- Adverse event reporting
- Mandatory education (GCP training, annual research modules, hazardous shipping, etc.)

Implementation Timelines

Year 1:
- Kick-off Meeting
- Brainstorming session for Action Plan development
- Creation of basic compliance assessment

Year 2:
- Ongoing monitoring & auditing
- Preliminary Action Plan Implementation

Year 3:
- Revision of Action Plan based on annual effectiveness assessment and compliance advisor feedback
Mature Action Plan Revisions – Year 3 and beyond

• Compliance with Standard Operating Procedures & HIPAA Guidelines for the Conduct of Clinical Research
  – Site self-assessments using CRO developed tools (quarterly requirement)

• Federal and State Funded Grantees to Comply with Applicable Laws and Regulations

• Increase & Maintain Research Oversight
  – Educate on revised SOP’s, IRB Policies and Procedures, HIPAA Investigator Guidelines

• Conflict of Interest Management
  – Verify compliance with COI Policies and Procedures
  – Annual COI disclosures to be completed and filed
  – Present potential COI issues to Compliance Department

Mature Action Plan Revisions – Year 3 and beyond

• Clinical Trial Device Studies
  – Expectation to follow SOP speaking to Medicare Device Billing
  – Maintain listing of all individual studies (incl. HDE’s) approved by FI

• FDA Amendments Acts
  – Attend training by CRO & Legal
  – Clinical Trial Registration requirements
  – Educate & document education on policy Integrity of Research

• Education of All Individuals Responsible for Research
  – GCP Training: Investigator, Research Support Staff, and Matrix Members
  – Annual Research Modules
  – Shipping of Hazardous Goods

• Annual Meeting Requirements for Matrix Team Members
  – Attend at least 2 of the 3 research compliance matrix meetings
Tool to Implement: Action Plan

### Compliance Objectives

<table>
<thead>
<tr>
<th>Compliance Objective</th>
<th>Source Reference</th>
<th>Implementation Required</th>
<th>Target Date</th>
<th>Quarterly Status</th>
<th>Applicable Period</th>
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<tbody>
<tr>
<td>Example: Uniform Billing</td>
<td>ANA, CMS</td>
<td>Conduct periodic reviews of DRG-30 records</td>
<td>01/2023</td>
<td>Q1</td>
<td>2023</td>
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<tr>
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<td></td>
<td>Document that claims were reviewed</td>
<td>01/2023</td>
<td>Q1</td>
<td>2023</td>
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<tr>
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<td>Document corrective action plan</td>
<td>01/2023</td>
<td>Q1</td>
<td>2023</td>
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Tool to Implement: Compliance Assessment

### CHS Clinical Research Compliance Assessment Tool

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Tool to Implement: Compliance Assessment

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Tool to Implement: Privacy Assessment

 partner for Efficiency: Conflict of Interest

- IRB utilizes the Conflict of Interest Disclosure form published by Corporate Compliance (separate from Financial Disclosure form)

- **Policy:** *Conflicts of Interest and Conflicts of Commitment in Research* policy outlines conflict of interest standards for Research Community
  - References Corporate Compliance Administrative policy related to Conflicts of Interest
  - Mandates a Research Conflict of Interest Review Committee
    - Legal
    - Chief Compliance Officer
    - Research Administration
    - Physician Liaison

- All completed Conflict of Interest Disclosure forms submitted to IRB are forwarded to Compliance

- All forms received are scanned into shared database accessible by Compliance, Research, Materials Management, and Pharmacy
Partnering for Efficiency:
Compliance Program Effectiveness Audit

- Annual Review conducted by Research Auditor in Audit Services
  - Evaluates Facility Compliance Advisor compliance with action plan expectations
    - *Can FCA speak knowledgeably about action plan items?*
    - *Does documentation evidence compliance activity throughout the year?*
    - *Were self-assessments completed and submitted on time?*
  - Each site scored based on audit findings
  - Results reported to Senior Management and the Board
  - FCAs required to complete and submit corrective actions for any deficiencies identified

Consistently Applying the Program Throughout a Multi-disciplinary System

- Research is conducted in a variety of settings throughout the organization:
  - Physician Practices
  - Hospital Departments
  - Ambulatory Care Clinics

- To be successful, research compliance program must be:
  - Flexible: To accommodate various locations
  - Consistent: Policies apply to everyone; exceptions are rare
  - Centralized: A centralized research community can promote a consistent approach to compliance
  - Transparent: Communication is essential to success. Facility Compliance Advisors must feel comfortable reporting issues or concerns.
Plan for Auditing and Monitoring

- Policies and Procedures
- Role and Responsibilities of Research Staff
- Reporting Process
- Identification of a Research Compliance Officer
- Effective Communications
- Education and Training
- Random and Scheduled Audits of Research (Clinical & Financial)
- Response to Reported Noncompliance

Education for Research Compliance

- Sites need to establish a minimum core requirement for research personnel
- Mandatory Research Education for Physicians to be Principle Investigators
- Sites may need to provide ongoing educational training on established schedules: Can be accomplished in ways to minimize time constraints
- Research Staff requires that certain standards are to maintained for compliance
- Financial and billing employees must be trained to understand the research components
- Nurses and non investigator physicians need training for research as well as general staff members
Institutional Review Board Auditing

• IRB’s should be conducting their own audits of studies or outsourcing this for:
  Random and/or “For Cause”
  Informed Consent
  Serious Adverse Events/Adverse Events/Deviations
  Conflicts of Interest
  Compliance to Continuing Reviews and Numbers of Subjects Enrolled

• IRB’s should be providing ongoing training for the Board and staff

Questions and Answers

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