

Implementing a Research Compliance Program in a Large National Healthcare System

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Presentation Overview

- Applying research compliance policies in many different community hospital and academic settings
- Importance of communicating and collaborating with national and local division management and compliance team members
- Oversight and monitoring of clinical trial billing, conflict of interest and research privacy and information security



Catholic Health Initiatives Mission

The Mission of Catholic Health Initiatives is to nurture the healing ministry of the Church, supported by education and research. Fidelity of the Gospel urges us to emphasize human dignity and social justice as we create healthier communities.



Catholic Health Initiatives (CHI)



CHI Healthcare Sites



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CHI Workforce

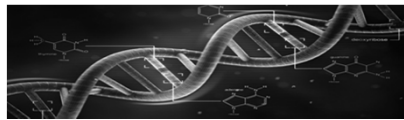


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PRECISION MEDICINE ALLIANCE
NAVIGATING PRECISION MEDICINE

- Joint venture launched in September 2016 between CHI and Dignity Health
- Advanced diagnostic tumor profiling in cancer treatment
- Plans to expand into cardiovascular risk and pharmacogenomics



7

Centralized Corporate Responsibility Structure

- CHI SVP, Corporate Responsibility Officer (CRO) reports to the CEO and Board of Stewardship Trustees
- Regional CROs report to the SVP with dotted line to division CEO
- Entity CROs report to Regional CROs with dotted line to hospital president
- Research compliance is part of the Corporate Responsibility Program(CRP) and reports to the VP, Corporate Responsibility



8

CHI Institute for Research and Innovation (CIRI)

- Connects CHI’s hospitals with system-wide initiatives, research programs, as well as private, government and industry research partners
- 3 CIRI components:
 - **Center for Clinical Research (CCR)** offers research management services; standardized P&P; division research managers, coordinators and financial analysts
 - **CIRI Oncology Research Alliance (CORA)** partners with CHI Cancer Centers to administer the NCI Community Oncology Program grant (NCORP)
 - **CIRI Institutional Review Board (CHIRB)** establishes CHI required research compliance education in coordination with Research CRO

NOTE: Some division research functions operate independently of CIRI and use other IRBs



Where is Research Conducted?

Answer. . . And more Questions!
CIRI-managed research sites
Sites using the CHIRB (including joint ventures)
Sites with CHI agreement to manage their own research operations
Other possible sites: <ul style="list-style-type: none"> • Are private practice physicians conducting research without the hospital or clinic’s knowledge? • Has hospital/clinic leadership approved research without knowing applicable requirements? • Are individuals conducting research without knowing it?



Common Rule Revisions and IRBs

- Common Rule revisions effective January 19, 2018 . . . then delayed until July 19, 2018 . . . then January 21, 2019 . . .
- How will each IRB approving research conducted at CHI facilities or with CHI data implement the Common Rule revisions?
 - CHIRB, affiliated medical school IRBs & central IRBs to name a few
- The IRBs also operate as CHI’s Privacy Boards under HIPAA— are they applying CHI’s privacy and information security standards when waiving or partially waiving research authorization?



Corporate Responsibility Program Clinical Research Addendum

Table of Contents

Clinical Research Addendum	1
Appendix A. Research Compliance Overview.....	2
Appendix B. The Belmont Report	5
Appendix C. Research Regulatory Review and Approval Process.....	7
Appendix D. Scientific Integrity	9
Appendix E. Grants, Contracts & Effort Reporting.....	10
Appendix F. Research Billing.....	12
Appendix G. Research Education and Training	14
Appendix H. Recommended Clinical Research Policies.....	17

Research Compliance Policies

- CIRI, CRP and division research leaders collaborate to create research compliance policies and avoid duplication:
 - CHI Research Policy (draft)
 - CHI Conflict of Interest policy with Research Exhibit
 - CHI Research Misconduct policy
 - CHI Use & Disclosure of PHI for Research Standard
 - CHIRB human research protection policies
 - CIRI grants management and clinical trial billing policies
 - Some division-level clinical research policies as needed



Clinical Trial Billing Policy Implementation

- CIRI or division research management office (non-CIRI sites) are responsible for :
 - Sponsored agreement negotiation
 - Create Medicare Coverage Analysis
 - Budgets and timelines
 - Research subject identification in EHR and notifications
 - Reviewing charges and reconcile accounts for accurate billing and coding

Clinical Trial Billing Monitoring

- Corporate Responsibility monitoring as a part of the annual monitoring plan
 - Compare sponsored agreement to budget, protocol, informed consent
 - Validate accuracy of Medicare Coverage Analysis
 - Ensure applicable CMS NCD and LCD elements met
 - Review claims for correct billing and coding
 - Review CHI technical fees and professional fees
- Some division self-monitoring conducted
- For-cause reviews
- Division internal audit reviews



Clinical Trial Billing Monitoring Challenges

- Obtaining clinical trial documents from many different sources in different divisions
- Different contractors providing revenue cycle operations functions in different divisions
- Understanding process variation based on different EHR capabilities
- CHI may not be a party to the sponsored agreement and may have limited access to information

Conflict of Interest (COI) Policy Implementation

- Annual Research COI disclosure using a third party tool
- Division research managers provide lists of researchers annually for upload and monitor completion with support from CIRI and CRP staff
- Research CRO reviews disclosures with financial interests and coordinates with CIRI, research managers and division CRP staff on COI management plans
- COI management plans provided to IRB



Conflict of Interest Monitoring

- Part of annual Corporate Responsibility monitoring plan
- Review researchers' disclosures and Open Payments data
- Validate COI management plan created if required and implemented
- Verify researcher completed required initial COI education and refresher education every 4 years

COI Management Challenges

- Continually communicating requirements and expectations to divisions
- Identifying all researchers throughout CHI
 - No central repository of researchers
- Monitoring and enforcing completion of annual disclosure
- Coordinating with academic medicine processes
 - Accept medical school disclosure if PHS-compliant processes in place
 - Limit researchers completing multiple COI disclosures with the same information



Research Privacy & Information Security Policy Implementation

- IRB protocol questions regarding information security, data storage and minimum necessary principles
- Information security questionnaire for exempt studies
- Continual education on research vs. QI/PI
 - CIRI Guidance on “What makes a project human subjects research?”
- Division data governance structures provide controls over access to data
 - Verify IRB approval before disclosing PHI for research
 - Release minimum amount of PHI necessary



Research Privacy & Information Security Monitoring

- Part of annual Corporate Responsibility monitoring plan
- Obtain list of approved expedited studies from IRB where consent and authorization have been waived or partially waived
 - Verify researcher is collecting data within the scope of IRB approval
 - Appropriately storing and de-identifying the data
 - Destroying the data according to the protocol
 - Not further disclosing the data or reusing the data outside the scope of approvals



Research Privacy & Information Security Challenges

- Non-employed researchers, including students may not be familiar with CHI Privacy and Information Security policies
- Affiliated medical schools may not be covered by HIPAA
- Implementing controls for access to data when researchers have direct access to data and report writing capabilities
- Creating more prescriptive procedures for use of data and images for research

Monitoring Discussion

How are you monitoring
these research areas?



Collaboration & Communication

- Continual communication with CIRI staff, division research managers/ coordinators and CRP team is vital
- Quarterly conference calls with division research staff and CRP representatives
 - Understand each division's structure and research climate/risks
- Participate in monthly CIRI Research Roundtables including all CHI research managers
- Provide education on new policies and risk areas



**DISCUSSION
AND
QUESTIONS**

25