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R12B Incorporating Research Compliance into Privacy and Security Risk Management for Healthcare Organizations

HCCA Research Compliance Conference ◆ Virtual◆ June 16, 2021

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Objectives

- Implement effective ways to integrate research compliance into the healthcare compliance framework
- Identify and manage unique areas locally and globally in research pertaining to privacy and security
- Work with other stakeholders in research to better monitor and manage risk at healthcare organizations

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Research Challenges in Healthcare Environments

- ✓ High risk due to highly regulated environment layered on top of healthcare
- ✓ Requirements for research data with PHI use and disclosure depends on how the organization is structured (e.g., OHCA, Hybrid)
- ✓ Multi-directional data sharing among research collaborators, sponsors, vendors, data coordinating centers, etc.
- ✓ Decentralized and many grey areas (quality improvement vs. research)
- ✓ Privacy and security considerations for innovative and international activities

Research does not often fit neatly into regulations or established healthcare environments or systems

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Research Compliance Programs

- ✓ Ensure compliance with research regulatory requirements in addition to those in healthcare
- ✓ Reduce organizational risks, ensure human research protections and the integrity of the research
- ✓ Essential to research program accreditation and federal assurances
- ✓ Provide structure for responding to agency investigations, inspections or audits of research activities and sites
- ✓ Focus on a unique and evolving area & provide education on policies and standards
- ✓ Create a more comprehensive healthcare compliance program for organizations conducting research

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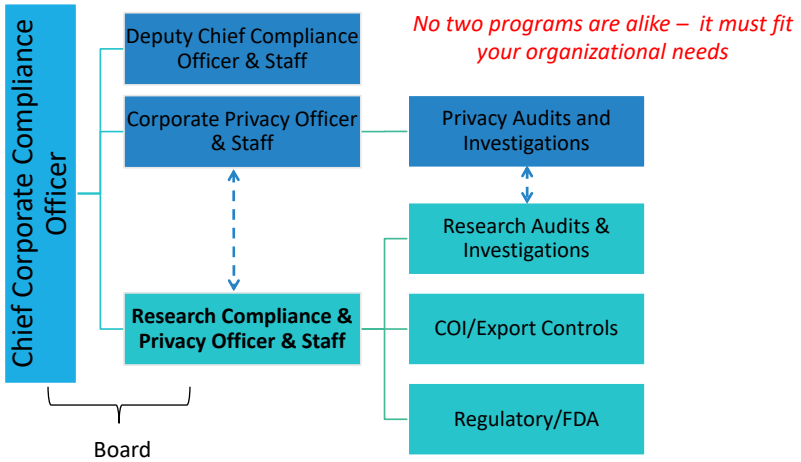
Organizational Structure Example



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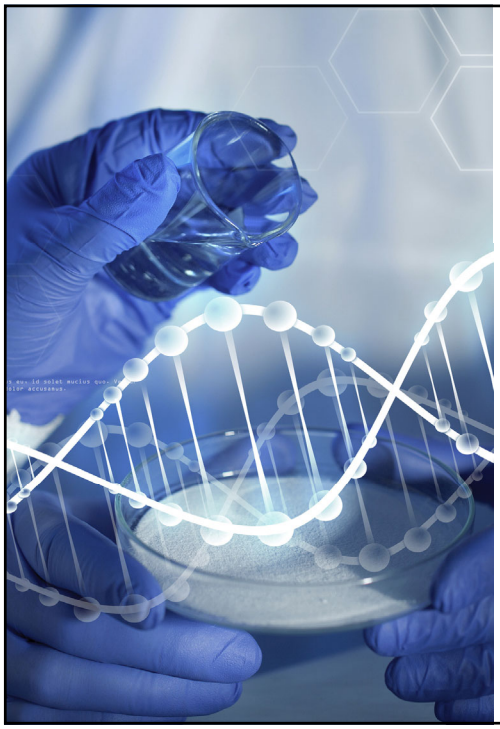

Common Research Activities Involving Data with PHI

- Reviews preparatory to research, retrospective chart reviews
  - Manual review of records or data pulls from EHRs or other data sources by an informatics group
  - Retrospective in nature, no direct interaction with research participants
- Observational studies, surveys, outcomes research, clinical trials, repositories
  - Prospective, interventional or direct interaction with research participants
  - Electronic and/or paper research documentation maintained and shared
- Advanced technology, computing and digital health trends:
  - Large data sets that utilize more sophisticated software, artificial intelligence
  - Electronic consent (e-consent) and data capture processes, remote interventions, video
  - Wearable or mobile devices with 3rd party software or apps, networked, remote monitoring

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Understand and Evaluate Your Healthcare Organization's Research Portfolio & Infrastructure

Clinical Research

- HRPP/IRB/Privacy Board
- Type of research
- Location/setting of research studies
  - Local/national/international

Clinical Data Groups/Programs

- Clinical Informatics/Data Science
- IT Security
- Data Repositories
- Data Strategy and Governance
- Health Information Exchanges

Infrastructure

- Research administration, operations, research support offices, regulatory and compliance committees/offices, legal, etc.
- Institutional research approval processes
- Electronic systems, data management (capture/storage/transfer), sharing
- Monitoring or auditing, reporting and management of privacy and security concerns in research and education
- System level research privacy & security committees

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Integrating Research Compliance into the Risk Management Framework

- Invest in resources/staff with experience, knowledge and expertise to effectively cover research activities
- Create policies that establish authority, roles and responsibilities
- Create a seat at the table with direct reporting to the board for large research programs
- Ensure regular communication with key stakeholders in privacy and security
- Liaise between research and corporate areas

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Examples of Integrating Research Compliance into the Privacy and Security RM Framework

Liaison with HRPP/IRB/Researchers

- Privacy & security incidents related to research reported to HRPP/IRB routed to Research Compliance for investigation and breach reporting (if app).
- Access to IRB systems & partner with IT Investigations for security issues.
- Privacy and security of research reviewed during audits and incidents are reported to HRPP/IRB.
- Notification to research participants regarding any breaches require coordination with IRB of record/HRPP for review of incident and correspondence.

Liaison with Corporate Compliance

- Research related incidents from the Compliance Help Line or detected from compliance monitoring/investigations routed to Research Compliance for further investigation.
- Large scale investigations and notifications to state and federal agencies regarding breaches require coordination with the Corporate Compliance Privacy Officer, Legal, Risk Management, IT Security and Research Leadership.
- Incidents included in overall metrics

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Identify and manage unique areas locally and globally in research pertaining to privacy and security

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Privacy & Security in Research Areas

- Clinical Research & Outcomes Research
- Global and International Activities
- Policies and Procedures
- System Level Committees
- Education & Training
- Auditing/Monitoring

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Privacy & Security Considerations

- Using and disclosing PHI for research purposes is NOT considered Treatment, Payment or Operations (TPO)
- Minimum necessary standard applies to research
- HIPAA authorizations, waivers by the Privacy Board and Reviews Preparatory to Research
- Other types of agreements may be needed: Data Use Agreement (DUA) for limited data sets
  - Accounting of PHI disclosures without the individual's authorization is required except for DUAs

- Who is the study sponsor, collaborator, data coordinating center?
- How will the information be used/stored/transferred/shared?
- Consent form/HIPAA authorization language and requirements?
- Other international privacy requirements?

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Integrating Privacy & Security Reviews into Research

Research Audits	• Review of research study agreements, documents & institutional approval • Assessment of privacy & security compliance and incidents
HIPAA Review/Rounding	• Rounding at research facilities that are also engaged in clinical activities • Assessment of safeguards for PHI, staff knowledge of HIPAA policies & procedures
DLP Monitoring	• Monitoring the movement of sensitive and highly sensitive ePHI over networks • Algorithm set by IT security and compliance based on risk
Sponsor Monitoring	• Monitoring external study sponsor access to EHR systems & activity • Assessment of IT requisition process & signed confidentiality agreements
Review of data pull & use	• Ensure minimal necessary data is pulled and shared by informatics groups • Review data use agreements with data pulls
Breach Reporting	• Ensure researchers are aware of methods and contacts to report potential breaches

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Global Engagement Considerations

- ✓ Understanding organizational global business activities and reach
- ✓ Surveying research community members
- ✓ Creating specific policies and procedures
- ✓ International remote work and travel involving employees, visiting scientists, scholars, etc.
- ✓ Utilizing system wide committees
- ✓ Setting up check points with study teams and committees
- ✓ Evaluating global privacy regulations
- ✓ Assessing exports of goods and services

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Internal GDPR Assessment Example

Intake Process

- Centralized checkpoint & process
- Review via checklist/ guidance document

Applicability Analysis

- Processing personal data of data subjects in scope?
- Territorial Scope: In territory OR outside territory offering goods or services and/or monitoring behavior of data subjects in territory?

Implementation

- If within scope, determine the institution's role & requirements (Controller and/or Processor role, legal basis, data flow assessment, Data Protection Officer, Data Subject Rights, etc.)

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Tools and SOPs for the Compliance Team

- Create standardized checklists, analysis tools and SOPs
- Review audit findings for trends and high risk areas
- Review institutional policies regularly to include regulatory updates
- Modify and update tools to keep up with the changing environment

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Resources for Researchers

- Clear and simple guidance documents
- Checklists for study teams
- Interactive training sessions
- Education sessions offered by all offices
- Monthly meetings with management/service-line directors
- Bi-monthly research update emails
- Contact information posted where research is conducted
- Year-end risk assessment with key stakeholders

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Conduct a Research Risk Assessment

- Interview stakeholders (e.g., investigators, research staff, administrators, research support staff and organizational leaders)
- How compliant is the organization?
  - History of breach reporting
  - Auditing and monitoring results/trends
- Evaluate regulatory agency priority areas and concerns
- Determine need and high risk areas to inform resources and budget development

Likelihood severity occurs	Potential Severity Rating: Minor	Moderate	Significant	Catastrophic
Very Likely	Moderate	High	Extreme	Extreme
Likely	Low	Moderate	High	Extreme
Unlikely	Very Low	Low	Moderate	High
Rare	Very Low	Very Low	Low	Moderate

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Stakeholders

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Committees

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Compliance Work Plan & Program Development

- Based on internal and external risk assessment
- Covers high risk and priority areas
- Incorporate into the annual Corporate Compliance work plan
- Present to the board for approval & disseminate to leadership
- Implement the work plan & evaluate results
- Adjust where needed and repeat cycle

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Final Takeaways

- Regularly evaluate research compliance needs and adjust based on changes to the organization's research program and portfolio
- Privacy and security will continue to become more complex so integrating research into compliance will help to manage risk for local and global activities
- Keep an eye on emerging technology and big data which will require working closely with key stakeholders outside of Compliance

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Thank You – Questions?

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