



A RESEARCH COMPLIANCE OFFICER'S DATA NIGHTMARE AND HOW TO WAKE UP FROM IT!

HCCA - Research Compliance Conference

June 2, 2020

Protiviti Perspective provided by Nikhil K., New Delhi

Internal Audit, Risk, Business & Technology Consulting

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SPEAKERS



Melissa Mitchell is the Chief Compliance and Privacy Officer for Shirley Ryan AbilityLab where she leads and maintains the Corporate Compliance and Privacy Programs, including day-to-day oversight and monitoring as well as strategic development of both programs to achieve the highest level of compliance. Previously, she was the Chief Compliance Officer and System Director of the Medical Staff Office at Sinai Health System, a multi-specialty safety net system on the Southwest side of Chicago. Before that, she was an analyst on the health law and business team at Wolters Kluwer, a legal publishing company. She began her career practicing law at a small civil litigation firm in downtown Chicago where she negotiated personal injury and workers' compensation settlements for individual clients and served as adviser and local counsel for corporate clients.

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Leyla Erkan is Protiviti's Global Healthcare Compliance Solutions Leader as well as the Midwest Healthcare Leader. Leyla has experience in acute and post-acute care settings with extensive experience in regulatory compliance, clinical research, HIPAA/HITECH, conflicts of interest, risk management, investigations, and governmental audit. Prior to joining Protiviti, Leyla served as the Chief Compliance, Research and Privacy Officer for the Shirley Ryan AbilityLab. Leyla was the Compliance Director and Privacy Officer for Ann & Robert H. Lurie Children's Hospital of Chicago. Leyla is a member of Northwestern University's Institutional Review Board and taught numerous courses on compliance and enforcement at Northwestern University.

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Ashley Huntington is the Privacy Officer for Cook County Health (CCH) in Chicago, Illinois. CCH includes John H. Stroger Jr. Hospital, an academic medical center; Provident Hospital, a community hospital; multiple clinics throughout Cook County; correctional medicine at Cermak Health Services within the Cook County Jail and Juvenile Temporary Detention Center; and the Cook County Department of Public Health. Ashley works closely with healthcare providers and workforce members on multiple compliance issues including regulatory requirements, compliance audits, and compliance education. She specializes in issues relating to privacy, including HIPAA Privacy and Security and state law compliance.

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OBJECTIVES



Protecting PHI and other forms of research data as it flows within and outside of an organization is a challenge and often raises significant privacy issues. We will discuss:

- Types of privacy issues, such as:
 - Using data to recruit patients,
 - Communicating on and triaging issues when deviations in research occur,
 - Data shared beyond the scope of research.
- Trends regarding:
 - How data is handled, potentially manipulated, and shared,
 - How compliance can best partner with other departments to support research while still safeguarding patient information.

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AGENDA



- 01** Privacy Fundamentals
- 02** Hypothetical #1: Recruitment
- 03** Hypothetical #2: Sharing Data
- 04** Hypothetical #3: Moving Data/After the Fact
- 05** Recommendations & Lessons Learned

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PRIVACY FUNDAMENTALS

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RESEARCH DEFINITION



The HIPAA Privacy Rule establishes the conditions under which protected health information may be used or disclosed by covered entities for research purposes. Research is defined in the HIPAA Privacy Rule as, “a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.”
See 45 CFR 164.501.

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RESEARCH PRIVACY BACKGROUND



- Researchers may obtain, create, use, and/or disclose individually identifiable health information. Under the Privacy Rule, Covered Entities are permitted to use and disclose protected health information for research with individual authorization (usually embedded in the informed consent) or without individual authorization (e.g., IRB/Privacy Board approval, preparatory to research, limited data set) under limited circumstances set forth in the Privacy Rule.
- A Covered Entity may always use or disclose for research purposes, which has been de-identified (in accordance with 45 CFR 164.502(d), and 164.514(a)-(c) of the Privacy Rule).

Source: <https://www.hhs.gov/hipaa/for-professionals/special-topics/research/index.html>

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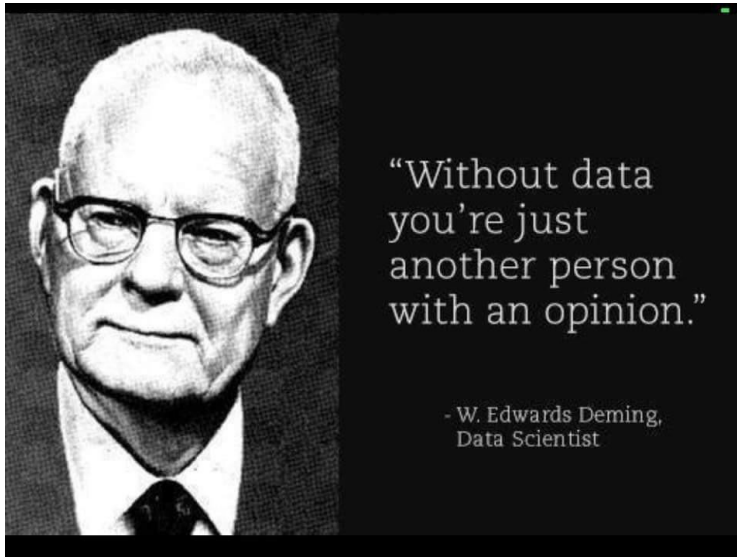
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| Area of Distinction | HIPAA Privacy Rule | HHS Protection of Human Subjects Regulations Title 45 CFR Part 46 | FDA Protection of Human Subjects Regulations Title 21 CFR Parts 50 and 56 |
|--------------------------|--|--|--|
| Overall Objective | Establishes a Federal floor of privacy protections for most individually identifiable health information by establishing conditions for its use and disclosure by certain health care providers, health plans, and health care clearinghouses. | To protect the rights and welfare of human subjects involved in research conducted or supported by HHS. Not specifically a privacy regulation. | To protect the rights, safety and welfare of subjects involved in clinical investigations regulated by FDA under 21 U.S.C. 355(i) and 21 U.S.C. 360(j). Not specifically a privacy regulation. |
| Applicability | Applies to HIPAA-defined covered entities, regardless of the source of funding. | Applies to human subjects research conducted or supported by HHS. | Applies to research involving products regulated by FDA. Federal support is not necessary for FDA regulations to be applicable. When research subject to FDA jurisdiction is federally funded, both the HHS Protection of Human Subjects Regulations and the FDA Protection of Human Subjects Regulations apply. |

Source: https://privacyruleandresearch.nih.gov/pdf/HIPAA_Booklet_4-14-2003.pdf

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HYPOTHETICAL BACKGROUND

You = Research Compliance Officer

- You rely on an affiliate's IRB for oversight of human subject research at your facility (IRB of record); IRB also acts as the Privacy Board for your facility.
- Researcher is interested in using your facility as a site for a multi-site sponsored neuro-trauma project by collecting blood samples from patients with certain conditions and submits a protocol to the IRB.
- Researcher intends to use reports generated from your facility's EMR to recruit patients for a study. A Central IRB has already approved the research.
- Subsequently, your IRB of record enters into a reliance agreement with the Central IRB and reviews and approves the protocol as well.

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HYPOTHETICAL #1: RECRUITMENT

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HYPOTHETICAL #1: RECRUITMENT



The researcher submits a request to Research Administration for access to your EMR and the reports. Research Administration contacts you and asks if they may grant this access.

What do you do?

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HYPOTHETICAL #1: IMPLICATIONS

| | |
|---|--|
| <p>A</p> <h3>Chicken and Egg Issues</h3> <ul style="list-style-type: none">Who approves this? The organization, the IRB or both?And who goes first? | <p>B</p> <h3>Focus on Policies</h3> <ul style="list-style-type: none">But how do they work in practice?Who is subject to them?Who knows about them? |
|---|--|

HYPOTHETICAL #2: SHARING DATA

HYPOTHETICAL #2: SHARING DATA



You are on the same page with the researcher in terms of recruitment, but you find out that the researcher intends to use cloud services to store and share information between his team at your facility and the researchers at other sites.

What do you do?

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HYPOTHETICAL #2: IMPLICATIONS

A

More Chicken and Egg Issues

B

Relationship between Research, Compliance, Legal, and Security

C

BAAs/Working with Large Cloud Storage Organizations

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HYPOTHETICAL #3: MOVING DATA/AFTER THE FACT

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HYPOTHETICAL #3: MOVING DATA/AFTER THE FACT



The researcher is still conducting the original study and has now accepted a position at another institution. The researcher wants to move the multi-site study to the new institution and take his data with him. Once the researcher has moved and you have resolved any data sharing issues (or so you think), you find out from your fellow Compliance Officer that the researcher still has and is using a laptop from your institution.

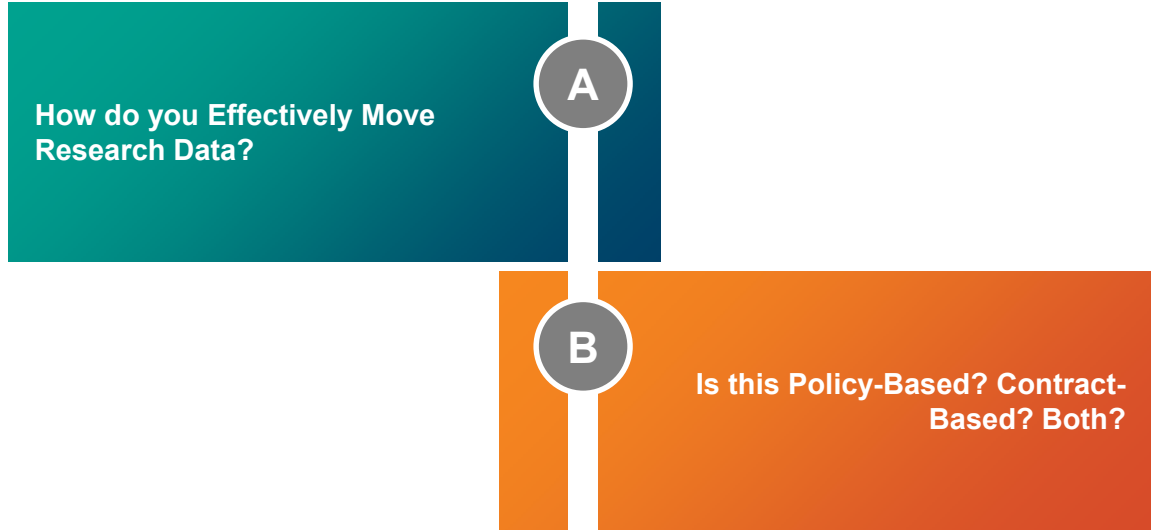
What do you do?

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HYPOTHETICAL #3: IMPLICATIONS



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RECOMMENDATIONS & LESSONS LEARNED

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RECOMMENDATIONS/LESSONS LEARNED



- Takeaways?
- What would you do differently?

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Thank You
Questions?

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