Incorporating Security Practices to Research Data in Light of HIPAA and ANPRM

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Research Administrators Forum

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Today's Discussion

- Review of HIPAA/HITECH and CA Privacy Laws impact on Research
- ANPRM related to Common Rule
- Examples of Sound Security Practices when handling Research Data

Privacy Laws Overview

- HIPAA Privacy
  - Protects use/release of protected health information (i.e., identifiable health information)
  - “Protected health information” includes any identifiable health information relating to the health of an individual, the care provided or payment for care – in any form
  - Administrative, physical, technical safeguards required to protect PHI
  - Went into effect April 2003

HIPAA Privacy Rule

- PHI may be used:
  - To treat the patient
  - To get paid for care provided
  - For healthcare operations
- All other uses generally require patient authorization (specific written consent)
- Notice of Privacy Practices

Use of PHI for Research

- Patient authorization required to use PHI for research
- Authorization must contain certain elements to be a valid HIPAA authorization
- Exceptions:
  - IRB Waiver
  - Limited Data Set
  - Preparatory to research (limited exception)
  - Decedents research

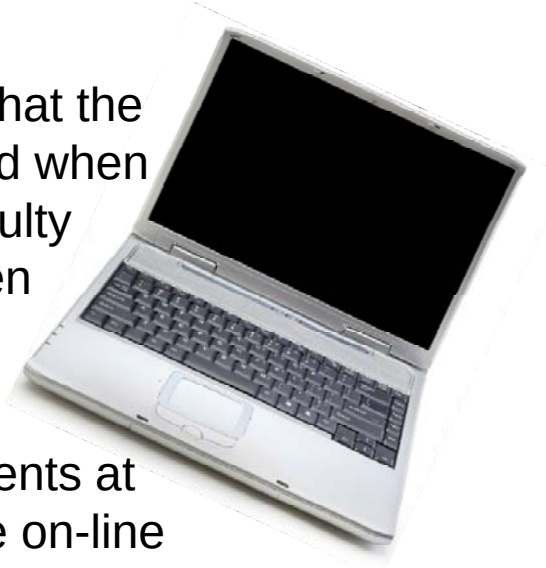
California Laws/HITECH

- Similar restrictions on healthcare providers, but more strict than federal law in certain areas (mental health, HIV tests)

- Duty to prevent unlawful use/release of health information – See former UCLA Researcher sent to jail for accessing fellow colleagues PHI.

- The Health Information Technology for Economic and Clinical Health Act (HITECH)
  - Expands HIPAA – creates breach notification requirement
  - 2011-2016: Financial Incentives for meaningful use of an Electronic Health Record
  - Increased Penalties for HIPAA Violations; criminal liability

Straight from the Headlines



- In November 2011, UCLA Health System announced that the health information of 16,288 patients was compromised when the home of a physician that worked for the UCLA Faculty Practice Group was burglarized and a laptop was stolen containing the patient health information.

- In September 2011, it was discovered that 20,000 patients at Stanford Hospital had their health information viewable on-line for nearly a year when a detailed spreadsheet provided to a billing contractor was posted on a public website. Class action lawsuit has been filed seeking $20 million in damages.

- DHHS announced a $1,000,000 Resolution Agreement Massachusetts General that stemmed from the loss of PHI of 192 patients after an employee had left hard-copy records containing PHI that included sensitive records discussing patients' treatments for HIV/AIDS on a subway.

OSTP and HHS releases "*Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay and Ambiguity for Investigators*" in July 2011

- Address concerns about IRBs review of *informational risk*, or those risks related to unauthorized release of research subject data, with the goal of balancing the protection provided by IRBs to human subjects with the progression of research.

- Seeks to extend HIPAA Privacy and Security Standards to all investigators in effect treating investigators as "covered entities" (Individually identifiable health information; Limited Data Set; De-identification of health information)

- **Potential Implications of applying HIPAA Standards to Research could result in increased administrative burden to the Research Administrator (e.g., biorepositories, data use agreements)**

Best Practices in Handling Research Data

- **USC Research Administrators should always be mindful of security and use discretion and common sense in dealing with research data.**

- **USC Investigators should not sign Data Use Agreements without consulting with OOC to ensure appropriate protections are in place.**

- Use encryption, passwords and other security devices to protect the security of information stored on computers, laptops, flash drives and mobile devices.
- Keep your passwords stored in a secure location, and never share your passwords.
- Log-off or shut down your computer if you will be away from your workstation for an extended period of time.
- Ensure that your workstation uses appropriate screen savers, particularly if you are located in a high traffic area.
- As a general rule, do not remove research data from the premises. If removal is necessary be sure that the information is encrypted or otherwise secured to prevent unauthorized use or access.

Want to know more?

- USC's HIPAA privacy and security policies and procedures are available on the USC policies website at www.usc.edu/policies or the USC Office of Compliance website at ooc.usc.edu.

- Review Research 300 series for Policy on Research, Research Authorization, Data Use Agreements