Information security and research

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How does regulations impact YOU?

- Understand exposure to PHI
- Appropriate Access is granted
- Protect PHI
- “Transport” of PHI
- Understand how you can share PHI
- Report any suspected problems where you are working
HIPAA & Research – What’s New?

• More HITECH
  • Consents for research
  • Data Breaches

• Encryption Policy
HITECH: Accounting for Disclosures

• HIPAA Privacy Rule Accounting for Disclosures

Under the Health Information Technology for Economic and Clinical Health Act; Proposed Rule, published May 31, 2011 contains provisions that, if enacted, will:

• Eliminate accountings for research disclosures
• Require access reports for electronic designated record sets, including access for research purposes, which would:
  • Go back 3 years
  • Include the following information:
    • Date and time of access
    • Name of person or entity making access
    • Description of information access, if available
    • Description of action by user, if available
FISMA Applicability to Research

- All information systems, electronic or hard copy which contain federal data need to be protected from unauthorized access. This applies to information associated with NIH grants and contracts.
- FISMA applies to grantees only when they collect, store, process, transmit, or use information on behalf of HHS or any of its component organizations.
- If grantees retain the original data and intellectual property of the research we do not need to be compliant with FISMA.
Common Rule: ANPRM Potential Privacy Changes

  - Jointly issued by the Office of the Secretary, HHS, and FDA
  - Only a proposal at this time
  - If changes accepted, implementation still a year or more away
ANPRM Potential Privacy Changes

- Aligning standards on what constitutes individually identifiable information, limited data sets, and de-identified data with HIPAA
- Biospecimens may be determined to be individually identifiable information due to advances in genomics
- Establishing data security, information protection, and data breach notification standards similar to HIPAA
- Eliminating IRB responsibility to determine adequate provisions to protect privacy of subjects and confidentiality of data.
Local Issues

• Unsecured and/or Loss of ePHI
  • Misplaced Flash Drives
  • Lost and/or Stolen Devices
  • Unmarked box of PHI for shredding thrown away by housekeeping

• Unauthorized Access of ePHI
  • Using clinical systems for personal use versus business need
  • PHI mistakenly posted on Facebook

• Unauthorized Disclosure of PHI
  • Discussion of patient’s history in public area in front of other patients
Services offered by Information Security

- Security Risk Assessments for IRB
- Contract review for Government requirements
- Incident Management
- Provide training and encrypted USB drives
- Track all the regulatory changes and determine impact
Contact Information

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Security Incidents and Questions to infosec@wusm.wustl.edu

Privacy Questions to hipaa@wusm.wustl.edu
Questions?