HIPAA Privacy Rule & Research: Update from HHS Office for Civil Rights

Christina M. Heide
Senior Health Information Privacy Policy Specialist
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Privacy Rule Balance

- Acknowledgment of importance of scientific research
- At same time, public concern with use of health information for research without patient knowledge/permission
- To balance, Rule protects patient right to privacy while allowing researchers access to health information
Brief Privacy Rule Background

• Applies to health plans and certain health care providers ("covered entities")
• Defines permissible uses and disclosures of identifiable health information, and their conditions, including for research
• Applies to all covered entities, regardless of whether Common Rule, FDA human subjects protections, or other rules also apply
• Two situations:
  – Covered entity is conducting research
  – Covered entity is source of information for research
Researcher Concerns

• As Rule implemented, heard researcher:
  – Concerns, e.g.,
    • Need harmonization with Common Rule
    • Too many forms
    • Accounting burden
    • De-identification standard too stringent
  – Questions on areas needing clarification, e.g.,
    • Clinical trial recruitment
    • Health services research
    • Research repositories/databases
What We Have Done

– Rule modifications in 2002 to streamline and further harmonize requirements with Common Rule
  • Simplified waiver criteria
  • Simplified accounting requirements
  • Streamlined authorization requirements
  • Created limited data set option
What We Have Done

- Issued extensive HHS guidance, developed in coordination with HHS research agencies
  - Clarifies application of Privacy Rule in various research contexts, e.g.,
    - Clinical research & IRB issues
    - Health services research
    - Research repositories and databases
  - Addresses interaction of Privacy Rule with Common Rule and FDA human subjects protections regulations
What We Are Doing

• Continue to review reported experiences of covered entities and researchers
  – E.g., HIPAA authorization issues
• Continue to collaborate and work with HHS agencies on additional guidance
  – E.g., Registry guidance
• Internal HHS Committee looking at issues related to harmonization of Privacy Rule, Common Rule, and FDA human subjects protections regulations
Compliance and Enforcement Experience

- As of April 2007, over 27,000 complaints received on issues spanning the full range of Privacy Rule requirements
- Approximately 1/3 of received complaints were eligible for investigation. All eligible complaints are investigated.
- Impermissible use or disclosure by health care providers is #1 allegation
- Research-related complaints mostly involve allegations of violations from patients upset at receiving recruitment calls from unknown researchers
Emerging Issues and Considerations

• Health IT
  – New privacy and security concerns
  – Potential to expand utility of information for research purposes

• Increased consumer concern generally with use of and access to genetic information

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What Would Be Helpful From the Study

- Collection of objective and current information that:
  - Identifies any actual challenges to researchers due to need to comply with Privacy Rule requirements, and
  - Differentiates mere misconceptions or varying entity-level policies or practices that may be resolved by guidance or training
For More Information

Fact Sheets, FAQs, Other Information:

http://www.hhs.gov/ocr/hipaa/
http://privacyruleandresearch.nih.gov/default.asp