



United States Department of  
**Health & Human Services**

*Office of the Secretary*  
**Office for Civil Rights (OCR)**

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

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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



# 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

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Fact Sheets, FAQs, Other Information:

<http://www.hhs.gov/ocr/hipaa/>

<http://privacyruleandresearch.nih.gov/default.asp>