

# Evaluating the Impact of the HIPAA Privacy Rule on NIH-Supported Research

NIH Presentation to the IOM Committee on Health Research and the Privacy of Health Information: the HIPAA Privacy Rule

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Lana Skirboll, Ph.D.  
Director  
Office of Science Policy, NIH



## **NIH's Support of IOM Study – A Disclaimer**

n NIH is providing financial support for part of the IOM study, i.e., the study committee's meetings and evaluation of data

n NIH is not involved in the design or implementation of the study

# Scientific Opportunities

- n Unprecedented scientific opportunities for translation of scientific discoveries into improved patient care
  - Powerful new molecular technologies
  - Sophisticated IT systems permit access to large amounts of patient data for research
  - The coming of personalized medicine

# Privacy Protection Comes First

- n Privacy protection is paramount
  - Fundamental and abiding ethical tenet of clinical research
- n Researchers understand the importance of public trust to ensure continued patient participation in research

# Privacy Protection Comes First

- n Longstanding system in place to protect privacy and confidentiality
  - Common Rule and FDA human subjects regulations
  - Strategies used by researchers to protect confidentiality (encryption, coding, agreements)

# Privacy Protection Comes First

- n Need to balance two goals/goods – protecting individual privacy and conducting research that serves the common good



# Initial HIPAA Implementation Challenges and Solutions

- n Some problems were due to newness of Rule, inexperience, and real misunderstandings
- n HHS educational documents were developed to clarify and guide

# Ongoing Harmonization Issues

- n Three sets of Federal regulations
  - Common Rule
  - FDA Regulations
  - HIPAA Privacy Rule
- n Differences in scope, definition, and application
- n Different requirements for informed consent and authorization

# Harmonization Issues

- n Do the differences really make compliance difficult?
- n Does the duplication provide added value, i.e., enhance privacy protection?
- n Is the impact greater on smaller institutions?

# Reports from the Field

- n The Rule presents challenges to smaller institutions – may limit the research participation of underserved populations
- n The Rule's requirements can make recruiting patients and accessing data (medical records research) more difficult – may affect scientific validity and robustness of study designs
- n The Rule can delay the initiation of some research studies – may affect research productivity and progress

# Reports from the Field

- n The Rule is having particular effects on certain types of research:
  - Multi-site collaborative research
  - Databases and repositories
  - Epidemiologic and surveillance research
  - Records and registry research
  - International collaborations

## Key Questions

- n Are the impacts isolated or reflective of a systemic problem?
- n How extensive are the problems?
- n Are current problems still the result of misunderstanding and/or over-interpretation?

## Key Questions

- n Is the complexity of the Privacy Rule and differences with the Common Rule and FDA regulations creating inefficiencies and barriers to research without additional privacy protection?
- n In sum, are there components of the Rule that are not value added?

# Key Questions

- n Will this become more problematic because of the increasing complexity of research?
  - n multi-site collaborative research
  - n international collaborative research
  - n use of sophisticated information systems

## Key Question

n How will research aimed at advancing the development of personalized medicine be affected?

# What is Needed to Address the Key Questions?

- n A comprehensive analysis that:
  - Distinguishes real barriers from problems resulting from misunderstanding
  - Explores whether there are specific areas of the Rule that could benefit from change or additional guidance
  - Covers the full spectrum of research
  - Is based on recent and quantitative data
  - Seeks input from patients, not just researchers

## Shared Goals

- n Enable research to discover new approaches to the diagnosis, treatment, and prevention of disease
- n Ensure the privacy of patients and confidentiality of their data
- n Enhance public health and the quality of life

**How can we  
ensure the  
right  
balance?**

