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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NIH’s Support of IOM Study – A Disclaimer

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

- NIH is not involved in the design or implementation of the study.
Scientific Opportunities

- 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

- Privacy protection is paramount
  - Fundamental and abiding ethical tenet of clinical research

- Researchers understand the importance of public trust to ensure continued patient participation in research
Privacy Protection Comes First

- 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

- Need to balance two goals/goods – protecting individual privacy and conducting research that serves the common good
Initial HIPAA Implementation Challenges and Solutions

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

- Three sets of Federal regulations
  - Common Rule
  - FDA Regulations
  - HIPAA Privacy Rule

- Differences in scope, definition, and application

- Different requirements for informed consent and authorization
Harmonization Issues

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

1. The Rule presents challenges to smaller institutions – *may limit the research participation of underserved populations*.

2. 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*.

3. The Rule can delay the initiation of some research studies – *may affect research productivity and progress*. 
Reports from the Field

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

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

- 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?

- In sum, are there components of the Rule that are not value added?
Key Questions

- Will this become more problematic because of the increasing complexity of research?
  - multi-site collaborative research
  - international collaborative research
  - use of sophisticated information systems
How will research aimed at advancing the development of personalized medicine be affected?
What is Needed to Address the Key Questions?

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

- Enable research to discover new approaches to the diagnosis, treatment, and prevention of disease
- Ensure the privacy of patients and confidentiality of their data
- Enhance public health and the quality of life
How can we ensure the right balance?