Beyond the HIPAA Privacy Rule: Enhancing Privacy and Improving Health Through Research

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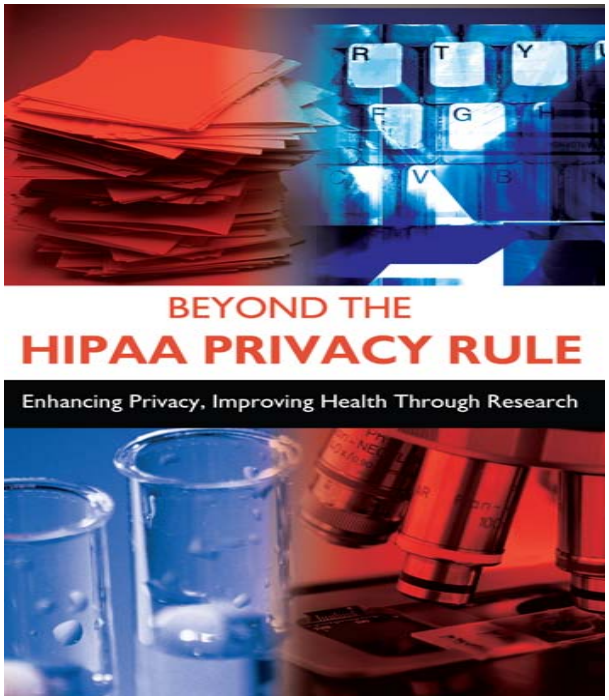
Enhancing Privacy, Improving Health Through Research



INSTITUTE OF MEDICINE

Overview

- About HIPAA
- Committee Charge
- Surveys of the Research Community
- Harris Survey of the Public
- Conclusions
- Recommendations

HIPAA

Health Insurance Portability & Accountability Act

A mandate in **HIPAA** required HHS to develop the **Privacy Rule** --» to provide federal protections for the privacy of health information

The **HIPAA Privacy Rule**:

Establishes conditions under which **protected health information** may be used/disclosed by **covered entities**.

PHI is identifiable health information held by a covered entity --» a health plan, health care provider, or health care clearinghouse

HIPAA

What is Protected Health Information (PHI)

- Name
- Geographic subdivisions smaller than a state, including zip code
- All elements of dates (except year)
- Phone / fax / email
- SSN
- MRN
- Health plan beneficiary numbers
- Account and license numbers
- Vehicle identifiers
- Device identifiers
- Web URLs
- IPN
- Biometric identifiers - (e.g. fingerprint or voice print)
- Photographic images or comparable
- Any other unique identifying number

HIPAA

"Covered entities" are health plans, health care providers, or health care clearinghouses

Covered Entities	Non-covered Entities
HMO	Independent consent management co.
Group heath plans	CROs
Medicare/Medicaid	Research foundations
VA Healthcare	Data warehouses/management
Uniformed Services Medical Program, Civilian health	Free Student health services
Indian Healthcare	Pharmaceutical companies
Researchers employed by a CE	Researchers not employed by a CE
Some universities or parts	Some universities or parts
Public health clinic part of a subject to public agency	Public health agency that does not perform activities subject to the Rule
Pharmacies	

HIPAA and Research

Research is a "systematic investigation, …, designed to develop or contribute to generalizable knowledge"

- **General Rule** – individual authorization required

- **Exceptions:**
  - Waiver from an IRB or Privacy Board (Minimal privacy risk, research not otherwise practicable)
  - Activities preparatory to research
  - Decedent research
  - Limited data set (no direct identifiers) with data use agreement
- **Accounting of disclosures** is required for a 6 yr period
- **De-identified** information is not protected by the Rule

Committee Charge

- To investigate the effects of the Privacy Rule on health research:
  - Examining the spectrum of health research
  - Looking at interpretation of the regulation vs. requirements of the regulation
- To seek ways to balance patient privacy against researchers' need for identifiable health information

Surveys of the Research Community

- **US Epidemiologists (IOM Commissioned)**
  Roberta Ness, University of Pittsburgh
  JAMA, November 14, 2007—Vol 298, No. 18

- **The HMO Research Network (IOM Commissioned)**
  Surveys of Researchers and IRB Administrators
  Ed Wagner and Sarah Greene, Group Health Center for Health Studies

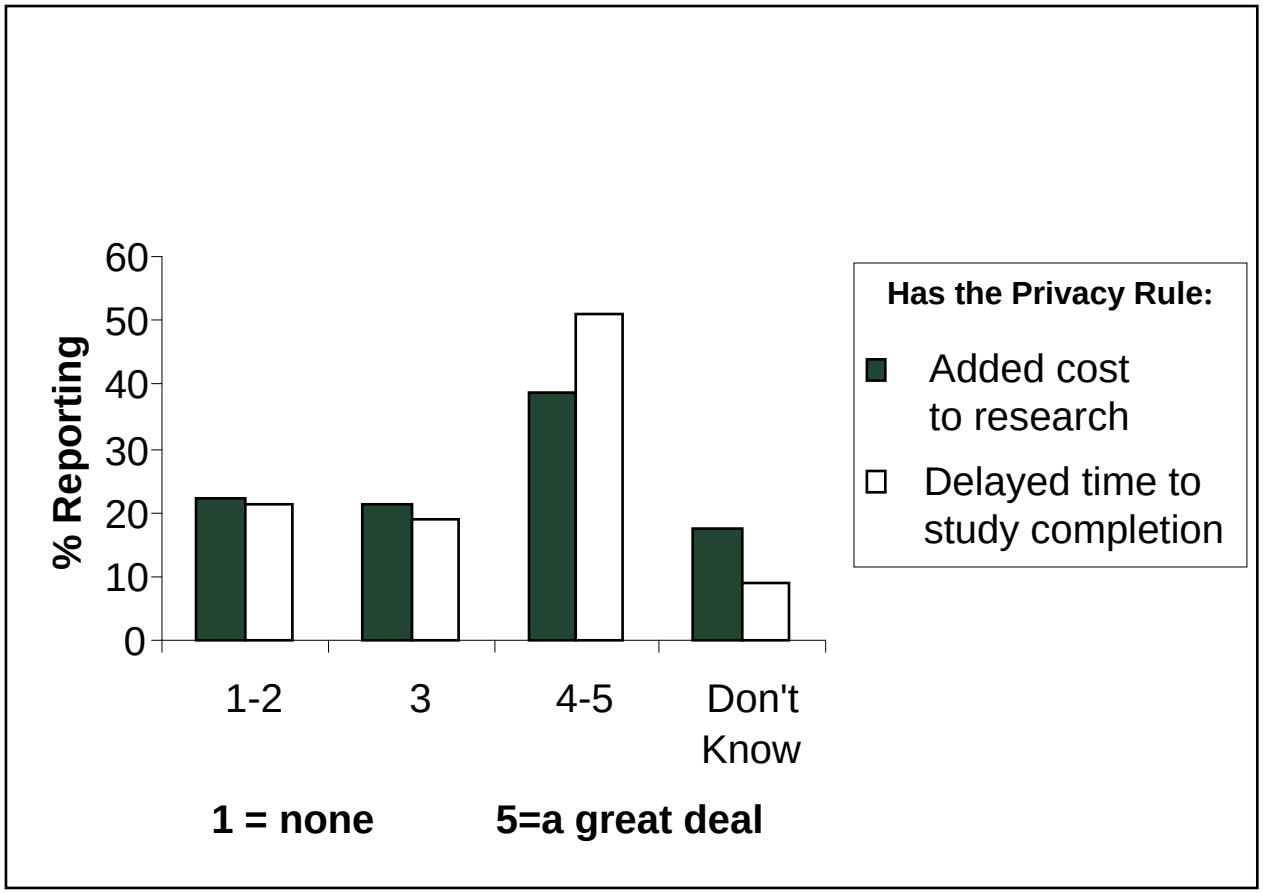
- **North American Association of Central Cancer Registries**
  Dennis Deapen, NAACCR

- **AcademyHealth Members**
  David Helms, AcademyHealth

- **AHA/ACC Members**

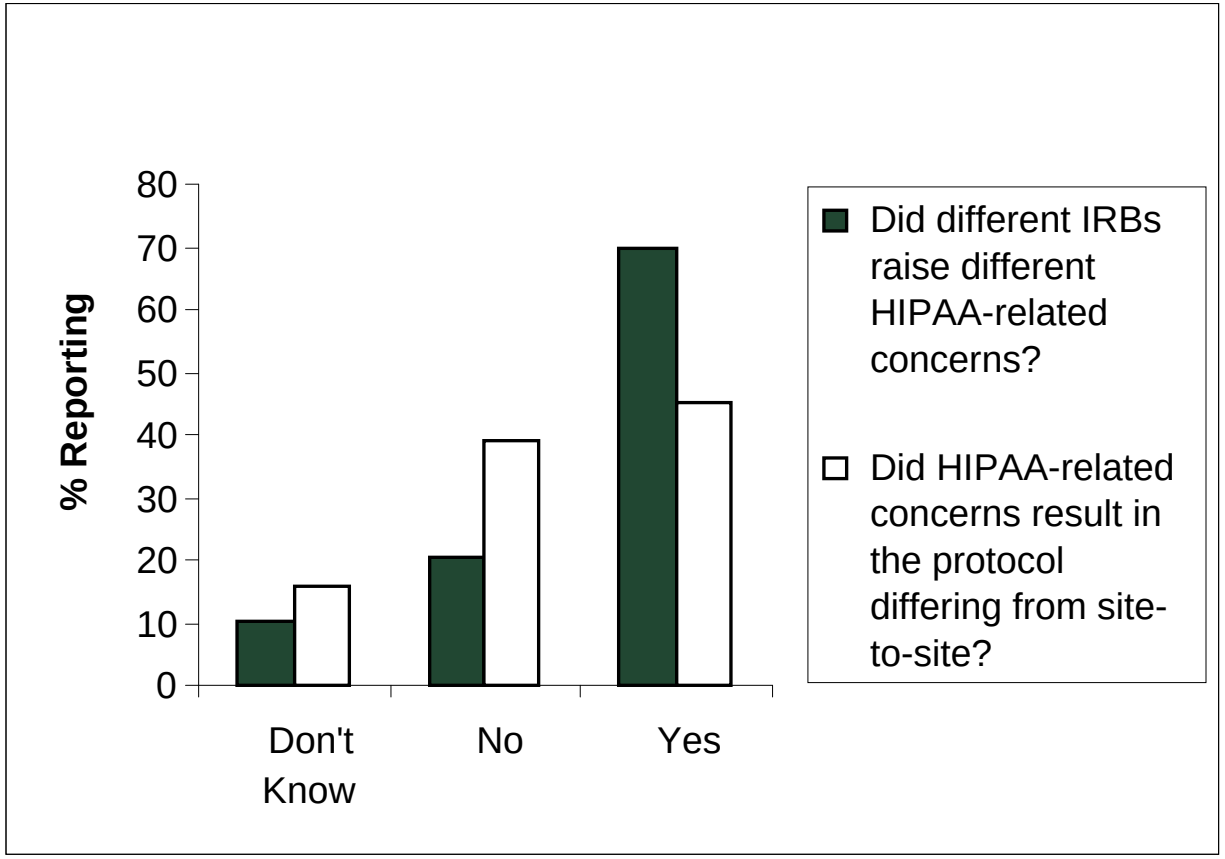
- **Qualitative Evidence Gathering Projects**
  - ASCO Structured Interviews and AAHC Focus Groups

Cost and Time: Survey of US Epidemiologists



Ness (2008)

Multisite Research: HMO Research Network



HMORN Researchers Survey

Summary of Researchers' Concerns

The Privacy Rule, as interpreted by covered entities, has:

- Increased the cost and time of research projects
- Complicated recruitment and increased selection bias
- Confused participants regarding their rights and protections
- Led researchers to abandon important studies
- Created barriers to the use of patient specimens
- Failed to create an effective way to conduct studies with de-identified data

Harris Survey:
Public Attitudes Towards Health Research And Privacy

- IOM commissioned survey by Alan Westin
- Web-based survey conducted Sept, 2007
- 2,392 respondents
- Included closed and open-ended questions

Harris Survey:
Trust in Health Researchers

"Health researchers can generally be trusted to protect the privacy and confidentiality of the medical records and health information they get about research subjects."

- **69**% agreed (11% strongly, 58% somewhat)
- **31**% disagreed (24% somewhat, 7% not at all)

Harris Survey:

How should researchers seek to get individuals' protected health information?

- **1**% - researchers do not need my consent at all
- **19**% - "my consent to use my personal medical and health information would not be needed as long as the study never revealed my personal identity and it was supervised by an IRB"
- **8**% - "I would be willing to give a general consent in advance to have my personally-identified medical or health information used in future research projects without the researchers having to contact me"
- **38**% - "researchers need my specific consent for all studies"
- **13**% - "I would not want the researchers to contact me or to use my personal or health information under any circumstances"
- **20**% - not sure

Summary of Public Survey Results

The majority of patients:

- consider **health research important** and are interested in research results
- **trust researchers** to protect privacy
- believe that current health **privacy protections are inadequate**
- express a desire for some form of **notice/consent** for information-based research

Committee's Conclusions

1) Privacy protections and health research both benefit individuals and society as a whole, so we should strive to support both to the extent possible.

Committee's Conclusions

2) The HIPAA Privacy Rule does not protect privacy as well as it should.

and

3) As currently implemented, the HIPAA Privacy Rule impedes important health research.

HIPAA: Flaws Related to Research

Lack of consistency

- HIPAA prevents future use of data, biospecimens - allowable under Common Rule
- HIPAA standard for de-identification more stringent than Common Rule
- Gaps in coverage

Variability in interpretation

- IRBs and Privacy Boards vary in interpretations - multi-site studies difficult. Overly conservative in many cases.
- Imprecise language: “practicable,” “adequate,” “minimal”, etc.

Increased burden

- Impedes research based on information only
- Delays, discourages, complicates and may invalidate research

HIPAA: Flaws Related to Privacy

Lack of protection

- Fails to provide the security, transparency, and accountability needed to protect privacy
- Although burdensome, procedures offer little real protection
- Gaps in coverage
- Overstates the ability of informed consent to protect privacy
- Variability in application

The HIPAA Privacy Rule Falls Short

- **Focus on consent is detrimental to research**
  - Selection bias can lead to invalid conclusions
  - Limits access to stored tissues and genetic data sets
  - Increases cost & time, reduces ability to recruit subjects
  - Results in researchers and hospitals “opting out” of research

- **Focus on consent does not protect privacy**
  - No protection for security breaches
  - Patients do not read or understand complex forms
  - Patients are often sick and incapable of making complex decisions

Committee Goals

To Improve

- ✓ **Privacy** and data **security** of health information.
- ✓ **Effectiveness** of health research.
- ✓ **Application** of privacy protections for health research.

Types of Recommendations Considered

- Changes in interpretation of the regulation through the release of new guidance documents
- Changes to the Privacy Rule regulations
- Changes to HIPAA (the Act)
- Beyond HIPAA (new legislation, HHS initiatives not specified by HIPAA, or voluntary activities by holders of health data)

Recommendations

HHS Should

- First and foremost: **develop a New Framework for protecting privacy in health research.**
  - Alternatively, **revise the Privacy Rule** and associated guidance.
- **Implement changes**, independent of the Privacy Rule, necessary for either policy option.

Beyond Consent: A New Framework

- Congress should authorize a new approach to ensuring privacy that would apply **uniformly** to all health research.
- The new approach would **enhance privacy protections** through improved security, transparency and accountability.
- **HHS should exempt health research from the HIPAA Privacy Rule**.

Beyond Consent: A New Framework

Should Do ALL the Following:

- Apply to **all** persons, institutions, & organizations conducting health research in the US, regardless of data source or funding.
- Be **goal-oriented**, rather than prescriptive
- Distinguish **interventional** from exclusively **information-based** research.
- Certify institutions with policies and practices to protect data **privacy** and **security**.
- Facilitate **greater use of de-identified** data in health research, and include legal sanctions for unauthorized re-identification.

Beyond Consent: A New Framework

Should Do ALL the Following:

- Require ethical oversight of research using PHI *without informed consent* that considers:
  - Measures to **protect the confidentiality** of the data
  - **Potential harms** from disclosure
  - **Potential public benefits** of the research
- Require strong data **security** safeguards.
- Include federal **oversight** and **enforcement** to ensure regulatory compliance.

Alternative Policy Option

HHS Should Revise the HIPAA Privacy Rule and Associated Guidance to:

- **Reduce interpretive variability** through revised and expanded guidance and harmonization.
- Develop guidance materials to **facilitate more effective use of existing data and materials for research.**
- **Revise some provisions** of the HIPAA Privacy Rule that currently hinder research but **do not provide meaningful privacy protections.**

Alternative Policy Option:

HHS Should Reduce Variability in Interpretation of HIPAA in Research

1. **Promote** "best practices" for privacy protection.
2. **Expand** use and usability of data with **direct identifiers** removed.
3. **Clarify** distinctions between "research" and "practice" to ensure appropriate oversight.
4. **Facilitate** appropriate oversight of identification and recruitment of *potential* research subjects.

Alternative Policy Option

HHS Should Facilitate Effective Use of Existing Data & Materials

1. **Allow** authorization for **future specified research**, with IRB oversight.
2. **Simplify** authorization for **interrelated research** activities.
3. **Clarify** the circumstances under which **DNA** samples or sequences are considered PHI.
4. **Facilitate linking** of health data from multiple sources for research.

Alternative Policy Option

HHS Should Revise Provisions of the Privacy Rule

1. **Reform** the requirements for the **accounting of disclosures** of PHI for research.
2. **Simplify** the criteria for **waiver of patient authorization** for the use of PHI in research.

Necessary Changes

Either Policy Option

1. **Safeguard** personal health information
2. **Protect** members of IRB and Privacy Boards who serve in good faith
3. **Disseminate research results** to study participants and the public
4. **Educate the public** about how research is done and what value it provides

Acknowledgments

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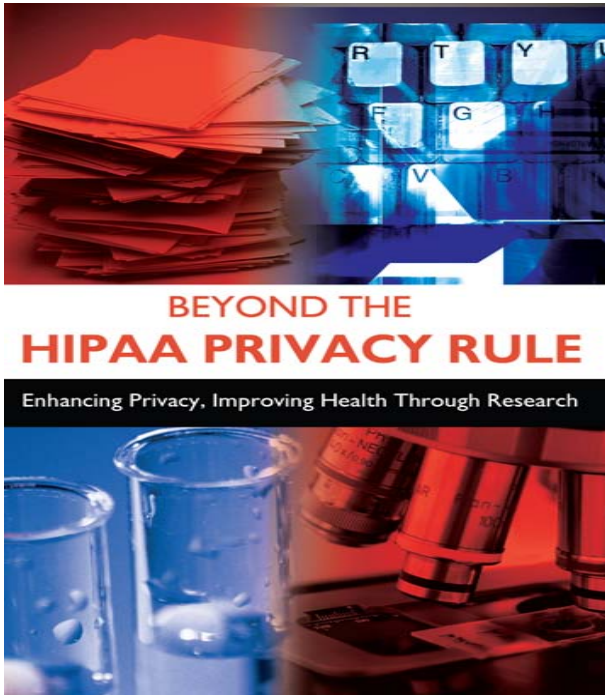
Study Funders

National Institutes of Health **National Cancer Institute** **Robert Wood Johnson Foundation**
American Cancer Society **C-Change** **American Society for Clinical Oncology**
Burroughs Wellcome Fund **American Heart Association**

For more information….



www.iom.edu/hipaa

Or

www.nap.edu