Overview of an ongoing IOM study on

HEALTH RESEARCH AND THE PRIVACY OF HEALTH INFORMATION: THE HIPAA PRIVACY RULE

Presented by:
Sharyl Nass, Ph.D.
IOM Study Director

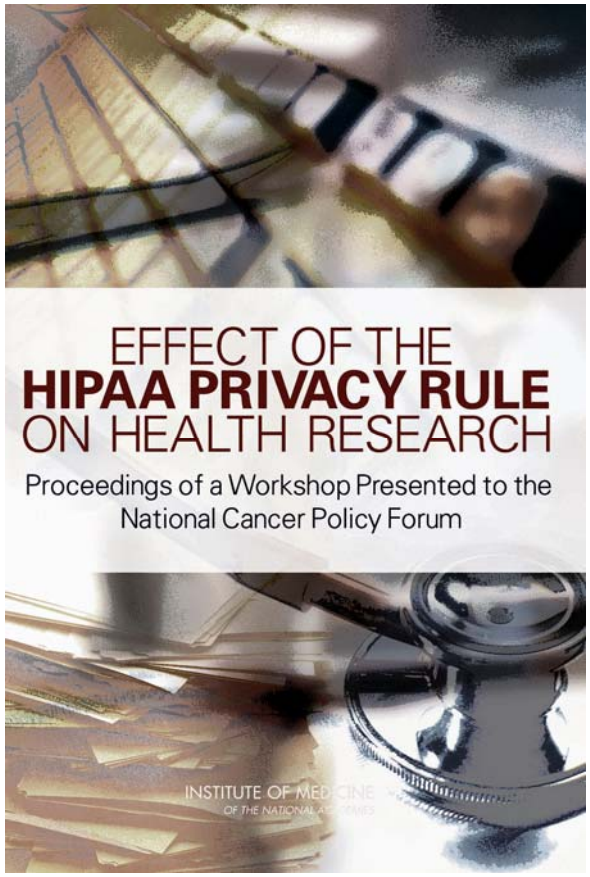
INSTITUTE OF MEDICINE

Effect of the HIPAA Privacy Rule on Health Research: Proceedings of a Workshop Presented to the National Cancer Policy Forum

June 16, 2006

Read the report online at:
http://www.nap.edu

(www.nap.edu/catalog/11749.html)



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An IOM consensus study was suggested by the President's Cancer Panel

Current list of funders:

NCI	**NIH**
ASCO	**AHA/ASA**
ACS	**Burroughs Wellcome Fund**
C-Change	**Robert Wood Johnson Foundation**

Committee Charge

An IOM committee will investigate the effects on health research of the Privacy Rule regulations implementing the Health Insurance Portability and Accountability Act of 1996 (HIPAA) section on Administrative Simplification and prepare a report.

As data and evidence allow, the needs and benefits of patient privacy will be balanced against the needs, risks, and benefits of identifiable health information for various kinds of health research. The committee will formulate recommendations for alterations or retention of the status quo accordingly.

Committee Charge

In conducting the study, the committee will consider:

- the range of study types, such as clinical trials, epidemiologic designs, research using tissue repositories and databases, public health research, and health services research, to the extent that available data and evidence allow;
- research carried out by the full range of sponsors: government, public and private academic, and for-profit sectors, including the pharmaceutical, biotechnology and medical device industries;
- the needs for privacy of identifiable personal health information and the value of such privacy to patients and the public.

Committee Charge

In conducting the study, the committee will:

- review provisions of the Privacy Rule relevant to health research, including those dealing with authorizations and accounting for disclosures of personal health information, de-identification of data, reviews preparatory to research, and others, and on reviewing them, may identify provisions that merit priority attention and analysis;
- take into consideration issues of interpretation and implementation of the Privacy Rule, as well as of harmonization with overlapping provisions of the Common Rule and FDA regulations, which have been in existence much longer;
- examine the potential impact of the Rule on public health research, on the recruitment of research subjects for studies, on carrying out research internationally, and on research using data and biomaterials in databases and tissue repositories.

IOM Data Gathering Activities

- **Survey of US Epidemiologists**

  PI: Roberta Ness, MD, MPH, University of Pittsburgh

- **Surveys of the HMO Research Network**

  PIs: Ed Wagner, MD, MPH and Sarah Greene, MPH
  Group Health Center for Health Studies

- **Harris Interactive Poll - public perceptions**

  PI: Alan Westin, LLB and Ph.D.,Center for Social & Legal Research

National Survey of Epidemiologists

- 13 societies of epidemiology
- Web-based survey
- Anonymous responses

Survey of Epidemiologists

Categories of Questions:

1) Quantitative responses
   - Types of data collection
   - Pre- and post rule recruitment
   - Experience obtaining waivers
   - Experience obtaining de-identified data

2) Perceptions on 5-point Likert scale
   - Ease and difficulty conducting research under rule
   - Impact of rule on privacy/confidentiality

Survey of Epidemiologists

Categories of Questions:

3) Case Studies
   - Would your IRB approve?

4) Open-ended qualitative data collection

Epidemiologist Survey Preliminary Overview of Results (analysis ongoing)

- Most respondents perceived Privacy Rule's impact to be strongly negative
- Concerns included variability in local interpretation
- Added cost and delay were common concerns

The HMO Research Network

<u>Proposed data gathering approaches</u>:

- **Survey of Cancer Research Network Investigators**
  13 CRN sites & collaborating academic institutions;
  50+ faculty members involved in population-based epidemiology, health services, intervention research.

- **Examine Database of HMORN / CRN projects capturing HIPAA-related processes**

- **Survey of HMORN IRBs**

Harris Survey

(public experience with and attitudes about health research and privacy)

- 10 closed-end questions for all respondents
- 1 four-part Agree/Disagree question for all respondents
- 6 closed-end questions for respondents who have participated in a health study
- 2 open-end questions, one for research study participants and one for persons whose personal information was released without consent
- 12 standard demographics

Proposed Study Timeline

Committee meetings and data gathering	Review process	Pre-pubs delivered	Final reports printed
June 2007 To June 2008	~Sept. 2008 To Nov. 2008	~ Dec. 2008	~Feb. 2009

Committee Membership

Lawrence O. Gostin, JD - (Chair)
Georgetown University Law Center

Paul S. Appelbaum, MD
Columbia University Medical Center

Elizabeth Beattie, Ph.D.
University of Michigan

Marc Boutin, JD
National Health Council

Thomas W. Croghan, MD
Mathematica Policy Research, Inc.

Stanley W. Crosley, Esq.
Eli Lilly and Company

Sandra Horning, MD
Stanford University School of Medicine

James S. Jackson, Ph.D.
University of Michigan

Mary Beth Joublanc, JD
Arizona Department of Health Services

Bernard Lo, MD
University of California, San Francisco

Andrew F. Nelson, MPH
HealthPartners Research Foundation

Marc Rotenberg, JD
Electronic Privacy Information Center

Wendy Visscher, Ph.D.
Research Triangle Institute

Fred Wright, MD
VA Connecticut Healthcare System

Clyde W. Yancy, MD
Baylor University Medical Center

To follow the project:

National Academies "Current Projects" website

http://www8.nationalacademies.org/cp/

or go to:

http://www.iom.edu/CMS/3740/43729.aspx