

HIPAA and Research

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

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Marcy Wilder
mwilder@hhlaw.com

HOGAN &
HARTSON



HIPAA and Research

- ∇ **HHS sought a balance: protect patient privacy and avoid creating undue barriers to medical research**

Privacy and the Common Rule

- **For almost 25 years the Common Rule had regulated research privacy**
- **IRB must determine that the protocol contains “adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data”**

HIPAA Did Not Regulate Research

- **HIPAA did not “regulate” research and was to operate independently of the Common Rule**
- **HIPAA regulated access by researchers to PHI held by covered entities**

- **HHS did not harmonize HIPAA with the existing regulatory framework for human subjects protection**

Comments for 2000 Rulemaking Did Not Promote Alternatives

- **HIPAA was the first comprehensive federal health privacy regulation**
- **Comments were largely focused on the negative impact privacy protections would have on health care and medical research**
- **Few proposed alternatives**

HHS Recognized the Research Provisions Needed Fixing

The 2002 Final Rule:

- **Added limited data sets**
- **Provided AOD alternative**
- **Simplified criteria for authoriz wvrs**

- **Implementation experience over the past few years has helped highlight the need for changes**

Sometimes Burdens are Heavy and Privacy Benefits Slim

- **Accounting for disclosures for research operating pursuant to an IRB waiver**

HIPAA and the Common Rule Diverge and Research Suffers

- **Future unspecified research**
- **Translating research authorizations
into unanticipated foreign languages**

HIPAA Creates a New Federal Standard for De-identification

- **Is the de-identification safe harbor to narrow?**
- **Is the statistician method a reasonable alternative?**
- **Are the liability burdens properly distributed?**

Advocating for Change

- **Issues must be clearly identified and policy alternatives must be developed and aggressively promoted**

Many HHS Agencies are Involved

- **Office of Civil Rights**
- **NIH**
- **FDA**
- **CMS**
- **AHRQ**
- **HRSA**
- **Office of E-Health Stndrds and Svs**
- **Office of the National Coordinator**

Many Important HHS Initiatives are Affected

- **NIH Research**
- **Pay for Performance**
- **Efforts to promote HIT**
- **FDA initiatives**

The Research Rules Can be Modified

- **Advisory committees, Congress and agencies within HHS itself have recognized that the HIPAA research provisions need improvement**

THANK YOU!

Marcy Wilder

Hogan & Hartson LLP

mwilder@hhlaw.com