

The HIPAA Privacy Rule: Impact on Clinical Research

HIPAA Audio-Conference

May 29, 2002

Julie Kaneshiro

DHHS Office for Human Research Protections

Phone: 301-402-7565

Fax: 301-402-0527

Email: jakaneshiro@osophs.dhhs.gov

Topics

- Background and Status
- Who and What is Covered
- Research Provisions
- For More Information



Background: Privacy Rule

- Health Insurance Portability and Accountability Act of 1996 (HIPAA)
- Publish privacy rule if no Congressional action by August 1999
- First Proposed Rule issued November 3, 1999
- Over 52,000 comments received

Background:

The “Final” Privacy Rule

- Issued on December 28, 2000
- Effective date: April 14, 2001
- Compliance date: April 14, 2003 (small health plans April 14, 2004)

Status of the Privacy Rule

- In response to public comments on the December 28 Final Rule, a new NPRM was released March 21, 2002.
- 30-day comment period ended April 26.
- Several proposed modifications to the Rule's research provisions.

**How would the current
Privacy Rule affect research?**

**What is the impact of the
proposed modifications?**

Who is Covered?

Public health
officials

Researchers

- Health care providers who transmit health information in electronic transactions, *including researchers who provide treatment to research participants*
- Health plans
- Health care clearinghouses

Law enforcement

Marketers

What is Covered?

De-identified
information

Human
biological
tissue

- Protected health information (PHI):
 - Individually identifiable health information
 - Transmitted or maintained in any form or medium
 - Decedents' health information

Key Point

- In general, the Privacy Rule requires patient authorization for the use or disclosure of PHI. **However, there are several exceptions...**

Uses and Disclosures: Specific Public Purposes

- Subject to various conditions:
 - **For research**
 - As required by law
 - For public health
 - To avert serious threats to health or safety
 - For health oversight activities
 - For law enforcement
 - Other

Research Provisions

- The Privacy Rule permits covered entities to use and disclose protected health information (PHI) for research conducted:
 - with individual authorization, **or**
 - without individual authorization under limited circumstances.

What Research is Affected?

- Research that uses existing PHI, such as:
 - Health services research
 - Clinical trials
- Research that includes treatment of research participants, such as:
 - Clinical trials

Note: The Privacy Rule **does not** override the Common Rule or FDA's human subjects regulations.

Research Use and Disclosure of PHI With Individual Authorization

- Authorization must include several elements regarding the use or disclosure of PHI; for example:
 - For research that involves treatment (i.e. clinical trials)—will address PHI to be generated.
 - For records research—will address use of existing PHI.

How the NPRM would change patient authorization requirements

- NPRM would require only a single authorization form for all uses and disclosures.
- NPRM would allow all required authorization forms to be combined with the informed consent.
- NPRM would eliminate separate authorization for research that involves treatment.
- NPRM would eliminate requirement to state if the use or disclosure will result in direct or indirect remuneration.

Research Use and Disclosure of PHI With Individual Authorization

- Patient authorization elements under the NPRM:
 - The information,
 - Who may use or disclose the information
 - Who may receive the information
 - Purpose of the use or disclosure
 - Expiration date or event (**NPRM: unless for a research database or repository**)
 - Individual's signature and date
 - Right to revoke authorization
 - Inability to condition treatment, payment, enrollment or eligibility for benefits—except for research-related tx
 - Redisclosures may no longer be protected by Rule

Common Rule vs. Privacy Rule

Research WITH patient permission

Common Rule/FDA Regulated



IRB review
Informed consent

Privacy Rule



Patient authorization

Research Use and Disclosure of PHI *Without Individual Authorization*

Under current Final Rule:

- 1) Obtain documentation that an IRB or privacy board has determined specified criteria were satisfied;
- 2) Obtain representation that the use or disclosure is necessary to prepare a research protocol or for similar purposes preparatory to research; **or**
- 3) Obtain representation that the use or disclosure is solely for research on decedents' protected health information.

Research Use and Disclosure of PHI *Without Individual Authorization*

One additional option under NPRM:

- 4) Only use or disclose “indirect identifiers” (e.g. zip codes, dates of service, age, death) for **research**, public health, or health care operations; **AND**

Require a data use agreement from recipient agreeing to use only for purpose provided and not to re-identify or contact individual.

~~8-3~~ Waiver criteria under NPRM

- 1) The use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements...

Waiver criteria...

- 1) Continued...
 - a) **an adequate plan to protect the identifiers from improper use/disclosure;**
 - b) **an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining identifiers or such retention is otherwise required by law; and**
 - c) **adequate written assurances that PHI will not be reused/disclosed to any other person or entity, except as required by law, for authorized oversight of research project, or for other research for which use/disclosure of PHI would be permitted by this subpart.**

Waiver criteria...

- ~~2)~~ The alteration or waiver will not adversely affect the privacy rights and the welfare of the individuals;
- ~~3)~~ **2)** The research could not practicably be conducted without the alteration or waiver;
- ~~4)~~ **3)** The research could not practicably be conducted without access to and use of the protected health information;

Waiver criteria...

~~(5) The privacy risks to individuals whose
protected health information is to be used or
disclosed are reasonable in relation to the
anticipated benefits, if any, to the individuals,
and the importance of the knowledge that
may reasonably be expected to result from the
research;~~

Waiver criteria...

~~(6) There is an adequate plan to protect the identifiers from improper use and disclosure;~~

~~(7) There is an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and~~

Waiver criteria...

~~(8) There are adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of protected health information would be permitted by this subpart.~~

Review and Approval Procedures

- To review and approve research proposals, IRBs and privacy boards may use:
 - “Normal” review procedures, or
 - Expedited review procedures.

Common Rule vs. Privacy Rule

Research WITHOUT patient permission

Common Rule



- IRB review—
4 waiver criteria

Privacy Rule



- IRB/Privacy Board Review—
8 3 waiver criteria
- Preparatory research;
- Research on decedents; or
- Indirect identifiers and data use agreement.**

Ongoing Research at Time of Compliance Date (4/14/03)

Under current Final Rule:

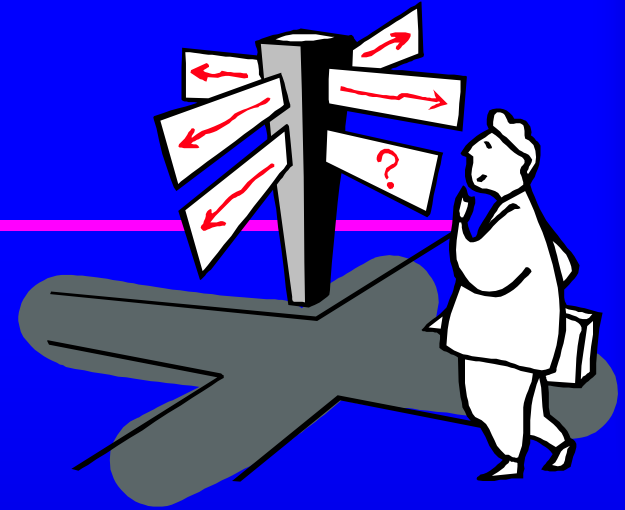
- Different “grandfathering” provisions depending on whether research involves treatment or not.

Ongoing Research at Time of Compliance Date (4/14/03)

Under NPRM:

- No distinction between research that involves treatment or and research that does not.
- Grandfathers-in the following if obtained prior to the compliance date:
 - Legal permission or informed consent for the research; or
 - An IRB waiver of informed consent under the Common Rule.

For More Information



OCR Privacy Website:

<http://www.hhs.gov/ocr/hipaa/>