

The Final HIPAA Privacy Rule: Impact on Human Subjects Research

September 9, 2002

Background: Privacy Rule

- Health Insurance Portability and Accountability Act of 1996 (HIPAA)
- DHHS to publish privacy rule if no Congressional action by August 1999
- First proposed rule – November 3, 1999
- First final rule – December 28, 2000
- New notice released – March 21, 2002
- Revised final rule – August 14, 2002
- Compliance date – April 14, 2003

Privacy Rule

Who is covered?

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

Not covered:

- Public health officials
- Researchers not engaged in HIPAA transactions
- Marketers
- Law enforcement

Privacy Rule

What is covered?

- Protected health information (PHI)
 - Individually identifiable health information
 - Transmitted in any form or medium
 - Decedent's health information

Not covered:

- Human biological tissue
- De-identified information

Key Point

In general, the Privacy Rule requires patient authorization for the use or disclosure of PHI.

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

Research Use and Disclosure of PHI with Individual Authorization

- Requires only a single authorization form for all uses and disclosures – eliminates separate authorization for research that involves treatment.
- Allows all required authorization forms to be combined with the informed consent.
- **Eliminates expiration date for all research authorizations.**

Authorization Must Describe...

- The information
- Who may use or disclose the information
- Who may receive the information
- **Purpose of the use or disclosure**
- Expiration date or event (can state “none” for research)
- 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

1. Obtain documentation that an IRB or privacy board has determined specified criteria were satisfied for a waiver
2. Preparatory to research
3. Solely for research on decedents' PHI
4. A limited data set AND there is a data use agreement from the recipient agreeing to use it only for the purpose provided and not to re-identify or contact the individual.

Limited Data Set Must EXCLUDE:

1. Names
2. Postal address information, other than town or city, State, and zip code
3. Telephone numbers
4. Fax numbers
5. Electronic mail addresses
6. Social Security numbers
7. Medical record numbers
8. Health plan beneficiary numbers
9. Account numbers
10. Certificate/license numbers
11. Vehicle identifiers and serial numbers, including license plate numbers
12. Device identifiers and serial numbers
13. Web Universal Resources Locators (URLs)
14. Internet protocol (IP) address numbers
15. Biometric identifiers, including finger and voice prints
16. Full face photographic images and any comparable images

Common Rule vs. Privacy Rule

Research WITHOUT patient permission

Common Rule



IRB review –
4 waiver criteria

Privacy Rule



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

Transition Provision

Effect of prior permission for ongoing research:
PHI may be used if there was

1. Informed consent of the individual to participate in the research
2. An IRB waiver of informed consent was given under the Common Rule

Accounting for Disclosures

- Upon request, must provide accounting for research disclosures made **without** individual authorization
- For 50+ records:
 - List of protocols for which PHI **may** have been disclosed, and
 - Researcher contact information.

Privacy Rule – Next Steps

- Office of Civil Rights
<http://www.hhs.gov/ocr/hipaa>
- NIH – CDC – FDA
 - Education programs
 - Web site
 - Brochures
 - Presentations to research community