Final HIPAA Privacy Rule:

The Research Provisions

National Research Summit
Audio Conference

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On August 14, 2002, the Revised Final Privacy Rule was born.

Compliance Date

- April 14, 2003
- April 14, 2004 for small health plans

The Privacy Rule has important implications for human research.

Topics

- Research Provisions
- For More Information
- Questions

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.

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

Authorization Must Describe…

- The information
- Who may use or disclose the information
- Who may receive the information
- Purpose of the use or disclosure (must be limited to a specific research study)
- Expiration date or event (can state "none" for research)
- Individual's signature and date
- Right to revoke authorization ("reliance exception" permits continued use/disclosure to maintain integrity of research study)
- Inability to condition treatment, payment, enrollment or eligibility for benefits—except for research-related tx
- Redisclosures may no longer be protected by Rule

Individual Authorization

- Allows all required authorization forms to be combined with the informed consent for research.

Common Rule vs. Privacy Rule

Research WITH patient permission

Common Rule/FDA Regulated

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IRB review
Informed consent

Privacy Rule

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Patient authorization

Research Use and Disclosure of PHI *Without* Individual Authorization:

Four Options:

- **OPTION 1:** Obtain documentation that an IRB or privacy board has determined that the following waiver criteria were satisfied:

3 Waiver Criteria

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…

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 research could not practicably be conducted without the alteration or waiver;

3) The research could not practicably be conducted without access to and use of the protected health information;

Research Use and Disclosure of PHI *Without* Individual Authorization

- **OPTION 2**: Obtain representation that the use or disclosure is necessary to prepare a research protocol or for similar purposes preparatory to research;

- **OPTION 3:** Obtain representation that the use or disclosure is solely for research on decedents' protected health information; OR

Research Use and Disclosure of PHI *Without* Individual Authorization

- **OPTION 4:** Only use or disclose limited data set/"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.

Limited Data Set Must EXLUDE:

(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) SSNs
(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; and
(16) full face photographic images and any comparable images.

Data Use Agreement Must:

(1) Establish the permitted uses and disclosures of such information by the recipient (i.e. for research, health care operations or public health);

(2) Establish who is permitted to use or receive the limited data set; and

(3) Provide that the limited data set recipient will…

Data Use Agreement…

(3) Continued:

(a) not use or further disclose the information other than as permitted by the data use agreement or as otherwise required by law;

(b) use appropriate safeguards to prevent use or disclosure of the information other than as provided for by the data use agreement;

(c) report to the covered entity any use or disclosure of the information not provided for by its data use agreement of which it becomes aware;

(d) ensure that any agents, including a subcontractor, to whom it provides the limited data set agrees to the same restrictions and conditions that apply to the limited data set recipient with respect to such information; and

(e) not identify the information or contact the individuals.

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
•Limited data set and data use agreement.

Research Provisions: Accounting for Disclosures

- Upon request, must provide accounting for research disclosures made **without** individual authorization (except for disclosures of the limited data set).

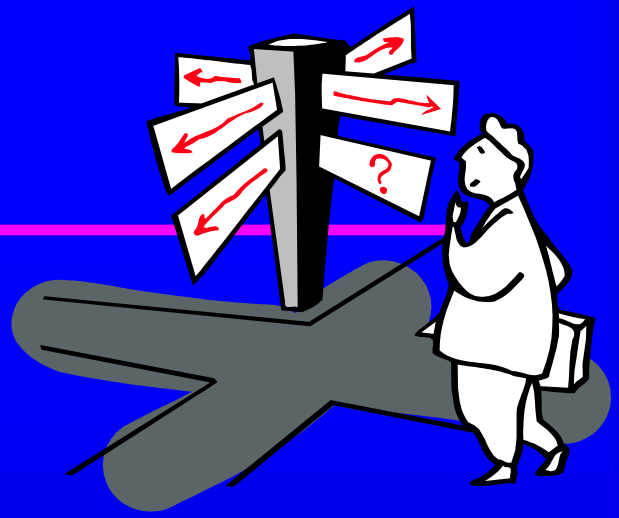
- For 50+ records:
  - List of protocols for which PHI **may** have been disclosed, and
  - Researcher contact information.

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

- 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 for the use or disclosure PHI;
  - 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/