Overview of HIPAA Rules for Epidemiologic Studies

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Topics

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

Health Insurance Portability and Accountability Act of 1996 (HIPAA)
Revised Final Privacy Rule

- Issued August 14, 2002
- http://www.hhs.gov/ocr/hipaa/whatsnew.html
- Effective April 14, 2003

The Privacy Rule has important implications for human research.

The Privacy Rule...

Protects the privacy of individually identifiable health information by establishing conditions for its use and disclosure by a health plan, healthcare clearinghouse, and certain healthcare providers.

Four Categories of Permitted Use and Disclosure of Protected Health Information

1. Use for
   - Treating the patient*
   - Obtaining payment for treating the patient*
   - Conducting health care operations, e.g., QC or training*

   *when patient is given Notice of Privacy Practices
2. Disclose to caregivers, with patient agreement
3. Disclosure for public health, law enforcement, government oversight: authorization not required
4. Disclosure for public policy reasons (e.g., research, marketing, fund raising: generally only with written patient authorization

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

Protected Health Information (PHI)

- Name
- All geographic subdivisions smaller than a state (and certain 3 digits of zip codes; see details)
- Dates except for year (and ages over 89; see details)
- Telephone, fax number, email address
- Social security number
- Medical record, health plan beneficiary, account, certificate/license number

Protected Health Information (PHI) (cont.)

- Vehicle and license numbers
- Device identifiers and serial number
- URLs, IP addresses
- Biometric identifiers
- Full face photographs
- Any other unique identifying number, characteristic, code

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.

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.

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

Research Use and Disclosure of PHI *Without* Authorization

1. IRB or Privacy Board waiver of Authorization requirement
2. Activity preparatory to research
3. Research is on decedent's information
4. Limited Data Set with Data Use Agreement
5. De-identify PHI
6. Disclosure to a public health authority or as required by law

1. Obtain waiver from an IRB or privacy board (specified criteria)

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; **AND**

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

2. Preparatory to Research

The disclosure is necessary to prepare a research protocol or other purposes preparatory to research (can remove no PHI). Researcher must obtain representation that:

- PHI is to be used solely to prepare a protocol or for a similar purpose
- PHI will not be removed from the covered entity AND
- PHI is necessary for research
- PI certifies to the covered entity that this is HIPAA compliant

3. Research on Decedents' PHI

Researcher must represent that:

- Use or disclosure solely for research
- PHI is necessary for research, and
- Individual is a decedent, and provide documentation upon covered entity's request.

4. Limited Data Set

Of the 18 PHI items, two may be disclosed

- Geographic subdivisions smaller than a state (but not address)
- Dates, including month and year, e.g., of treatment, birthdate, death

Only for research, public health or health care operations and,

Requires data use agreement

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) 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.

5. De-identified Data

- Contains none of the 18 PHI items
- No longer PHI
- Can contain a code to re-identify

6. Disclosure to a Public Health Authority or Required by Law

- Disclosure without Authorization permitted if required by law or for public health activities.
- EXAMPLE: Adverse event reporting to a sponsor, FDA, NIH, cancer reporting
- A covered entity may disclose PHI related to an adverse event to NIH if required to do so by NIH regulations. Even if not required to do so, the researcher may disclose adverse events to NIH as a public health authority.

Research Use and Disclosure of PHI Without Individual Authorization

SO…How will this work??

- For IRB-approved research with a waiver of authorization, not much differently than now.
  - IRB (or HIPAA board) will do HIPAA compliance review
  - Will covered entities honor your waiver or require their own review?

Research Use and Disclosure of PHI Without Individual Authorization

SO…How will this work??

- For the other options for disclosure without individual authorization (limited dataset, de-identified data, preparatory to research, decedents) HIPAA does not require IRB review: researcher certifies compliance
- Will providers accept?

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

- No distinction between research that involves treatment and research that does not.

- Grandfathers-in the following if obtained prior to the compliance date (can be broader than specific study):
  - Legal permission or informed consent for the research; or
  - An IRB waiver of informed consent under the Common Rule.

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

- If enrolling new patients after 4/14/03 and informed consent is required, for previously IRB approved consent must add HIPAA AUTHORIZATION ADDENDUM TO INFORMED CONSENT
- Do not need to resubmit for IRB approval if form is not modified (USC policy)
- But, incorporate HIPAA authorization into consent at next IRB annual continuation review (USC policy)

Accounting for Disclosures

- A covered entity is generally required to account for PHI research disclosures made without Authorization.
- Including for research disclosures of PHI for:
  - Reviews preparatory to research
  - Research using decedent's PHI
  - Research under a waiver of Authorization (including waivers that meet the transition provision requirements)
  - Disclosures to public health authorities or sponsors
  - Most disclosures mandated by law.

Types of Accounting

- Generally
  - (Date, recipient, recipient address if known, what was disclosed, purpose)
- Multiple disclosures to same person for same purpose
  - (Date; recipient; recipient address if known; purpose; frequency, periodicity or no. of disclosures, date of last disclosure)
- Research accounting for PHI of 50 or more individuals
  - (Name of protocol, description of protocol or research activity and PHI disclosed, date or period of time during which disclosure occurred or may have occurred and last date of disclosure, name, address, and phone no. of sponsor and recipient, statement that the PHI may or may not have been disclosed for a particular protocol or research activity)

Accounting – When NOT needed

Accounting is NOT needed for disclosures of:

- ✓ PHI in Limited Data Sets with Data Use Agreement
- ✓ PHI made pursuant to an Authorization (or informed consent that meets the transition provision requirements)
- ✓ PHI to the individual
- ✓ Disclosures made before April 14, 2003
- ✓ De-identified health information

Revoking an Authorization

- Individuals have the right to revoke their Authorization.
- EXCEPT, covered entities may continue to use or disclose PHI that was obtained before a revocation if "necessary to maintain the integrity of the research study." (Reliance exception)
- For example, researcher can continue using PHI to account for a subject's withdrawal from study.

State & Regional Cancer Registry

- State-mandated disease registries (like regional registries) are not HIPAA-covered entities.
- None of this applies to them.
- They may release fully identified, partially identified and de-identified data as permitted by state law.

State & Regional Cancer Registry

- May continue to access and remove PHI from covered entities (hospitals and physicians) for any purpose permitted by state law.

Postscript: NIH Funding

The HIPAA Privacy Rule and Research

Della M. Hann, Ph.D. NIH Office of Extramural Research

Privacy Rule and Roles

- **Role of Research Community**
  - **Determine if they are affected by the Privacy Rule when developing research applications/proposals.**
- **Role of Office of Civil Rights (OCR)**
  - **Oversight and enforcement of the Privacy Rule.**
- **Role of NIH**
  - **Work with DHHS to provide information about the Privacy Rule specific to the research community.**
    - » **NIH NOT INVOLVED IN ENFORCEMENT**
    - » **NIH WILL ASSUME COMPLIANCE FROM GRANTEES & CONTRACTORS**

How may the Privacy Rule affect NIH grant application/research contracts?

- For research involving covered entities..
  - **<u>May</u> influence plans for acquiring and accessing data that includes PHI**
  - **As a result, the Privacy Rule <u>may</u> affect the feasibility, design, and costs of the research**

How will the Privacy Rule affect NIH grant application/research contract processes?

- **As with any issue that can affect the feasibility,design, and costs of research…**
  - **Investigators may discuss the issue, as needed, in the research plan/technical proposal and budget/business proposal**
  - **No need to change general instructions for the Research Plan in the PHS 398**
- **In some cases, RFA's, PA's, and RFP's…**
  - **Could indicate the need to include plans for acquiring data under the Privacy Rule**
  - **Therefore, review criteria or statement of work could be augmented to include adequacy of such plans.**

How will the Privacy Rule affect NIH grant application/research contract processes?

- **Note: Privacy Rule does not replace or act in lieu of human subject protections in 45 CFR 46**
  - **No changes needed in the instructions for Human Subjects in PHS 398 for grants or Section L in the solicitation for research contracts.**
  - **If the PI/Offerer considers that implementation of the Privacy Rule will affect the adequacy of protections against research risks, they may want to discuss this in the Human Subjects section/Section L.**
- **Discussion of compliance with the Privacy Rule is not required.**

How will the Privacy Rule affect NIH grant application/research contract processes?

- **Peer Review**
  - **For Grants:**
    - » **Continue to use review criteria found in PHS 398**

      http://grants1.nih.gov/grants/funding/phs398/phs398.html
    - » **Continue to use NIH Instructions to Reviewers for Evaluating Research involving Human Subjects**

      http://grants1.nih.gov/grants/peer/hs_review_inst.pdf
  - **For Research Contracts:**
    - » **Continue to use review criteria described in Section M of the solicitation**
    - » **Continue to use NIH Instructions to Reviewers in Manual Chapter 6315-1**

http://www1.od.nih.gov/oma/manualchapters/contracts/6315-1/

How will the Privacy Rule affect NIH grant application/research contract processes?

- **Peer Review**
  - **Reviewers are NOT evaluators of Privacy Rule compliance – they are not OCR**
    - » **They do NOT know or need to know HIPAA status of the investigator or institution***
  - **Perceived compliance/non-compliance with the Privacy Rule is NOT a factor in scoring scientific merit for applications***

* **Unless the RFA, PA or RFP specifically requests this information and adds to the review criteria**

How will the Privacy Rule affect NIH grant application/research contract processes?

- Peer Review
  - **Any reviewer comments about the feasibility, design, data sharing plans, budget/costs, etc. – including comments about how Privacy Rule could affect these issues -- should be included in the summary statement (grants) or technical evaluation report (contracts).**
  - **In most cases, comments about the Privacy Rule will be part of an administrative note to alert the PI and program staff.**

How will the Privacy Rule affect NIH grant application/research contract processes?

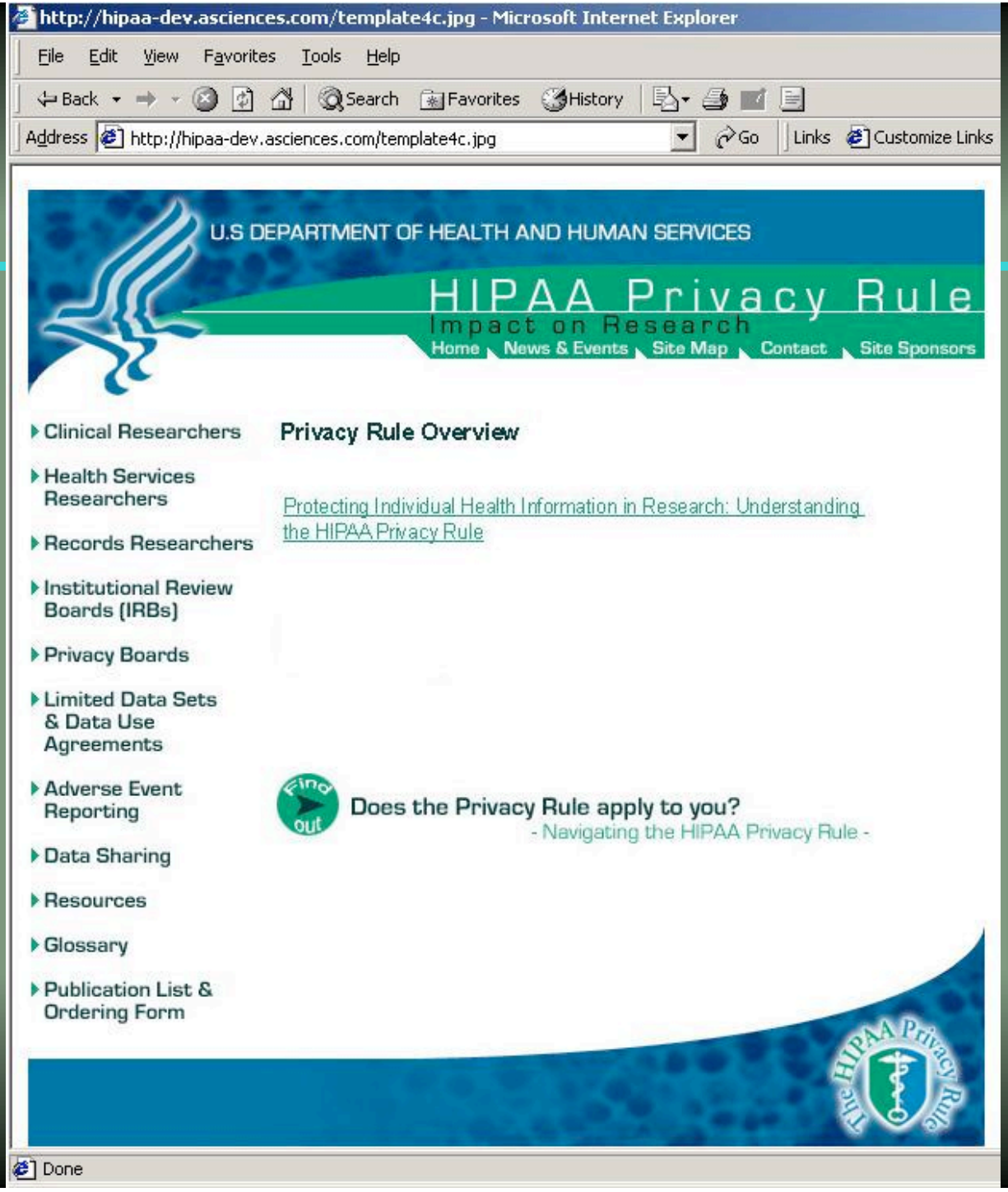
- Award Decisions
  - **Will continue to base on scientific/technical merit, programmatic needs, costs (contracts), and availability of funds**
    - » **Program staff/Contracting Officers will continue to discuss and seek resolution any issue or problem noted in the summary statement prior to funding**
  - **NIH does NOT require or record compliance/non-compliance with the Privacy Rule – we are not the enforcer!**

How will the Privacy Rule affect NIH grant application/research contract processes?

- Progress Monitoring
  - **PI's should contact program and grants management staff/contract officers if they encounter situations that significantly delay, change the study design/procedures, or change the costs**
  - **NIH staff will evaluate situations on a case-by-case basis to determine how to handle, e.g., change in scope, supplemental funding, no-cost extensions, etc.**

NIH's Role in Implementing the Privacy Rule

- The Office for Civil Rights asked Departmental research agencies to develop educational materials for researchers.
- NIH is leading the cooperative effort with FDA, CDC, AHRQ, and OHRP.
- NIH coordinates this effort with the assistance of Departmental committees and internal NIH working groups.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Health Services Researchers
Records Researchers
Institutional Review Boards (IRBs)
Privacy Boards
Limited Data Sets & Data Use Agreements
Adverse Event Reporting
Data Sharing
Resources
Glossary
Publication List & Ordering Form
Privacy Rule Overview
Protecting Individual Health Information in Research: Understanding the HIPAA Privacy Rule
Find out
Does the Privacy Rule apply to you?
- Navigating the HIPAA Privacy Rule -
The HIPAA Privacy Rule
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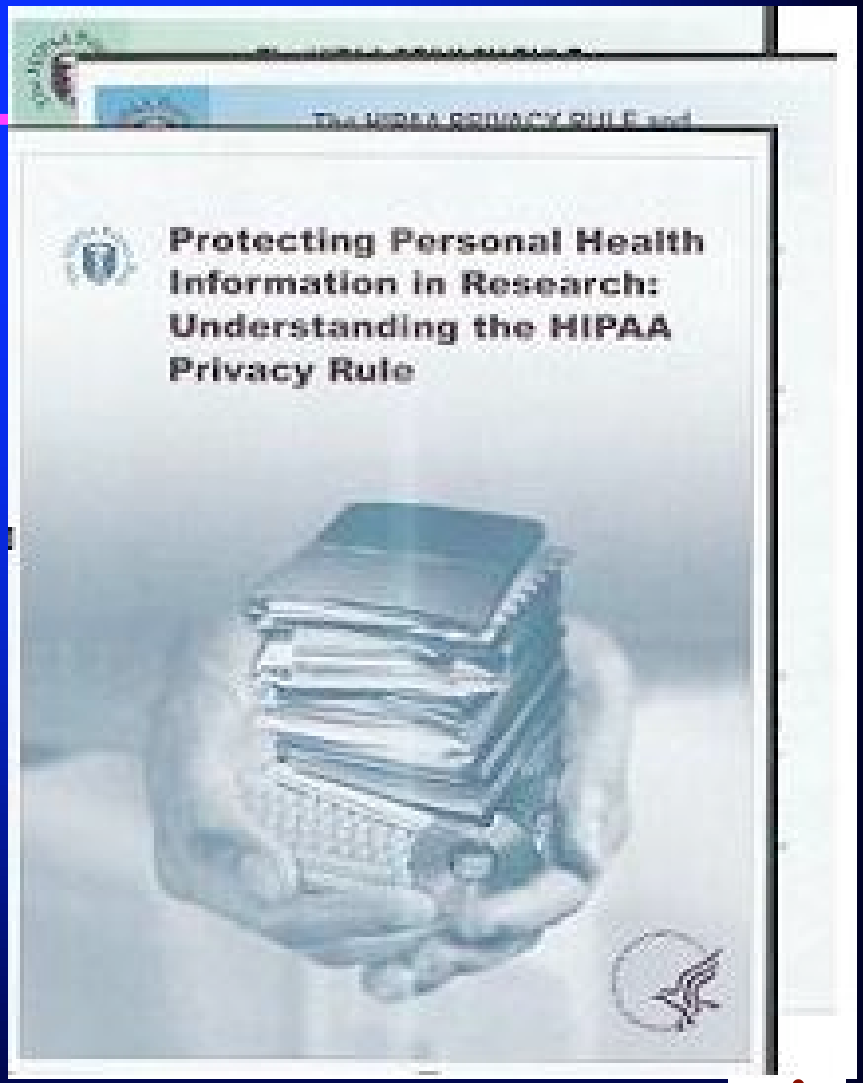
Educational Materials

Two Booklets: *Understanding the Privacy Rule*

Data Sharing with the Privacy Rule

Seven Fact Sheets: Clinical Research, Records Research, Health Services Research, IRBs, Privacy Boards, Limited Data Sets, Adverse Event Reporting

Additional Materials: Model Authorization Language, Decision Trees, FAQs



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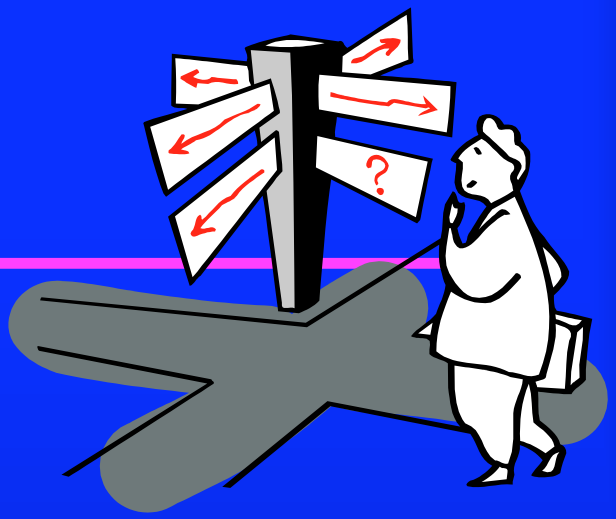
For More Information



OCR Privacy Website:

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