

**Occupational and Environmental Safety and Health
University of Illinois School of Public Health**

Ethical Issues in Human Research

Sofia, Bulgaria

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Privacy & Confidentiality



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RESEARCH

**A Systematic Investigation
Including
Development, Testing, and Evaluation
Designed To Develop Or Contribute To
Generalizable Knowledge**



INSTITUTIONAL REVIEW BOARD

Established to protect the
rights and welfare of
human subjects in research activities.



INSTITUTIONAL REVIEW BOARD

Review Principals

- **RESPECT FOR PERSONS**

Recognition of the personal dignity and autonomy of individuals

- **BENEFICENCE**

Protection of persons from harm by maximizing benefits and minimizing risks

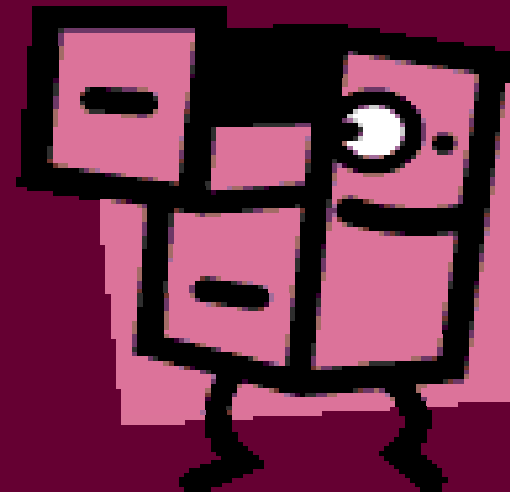
- **JUSTICE**

Provision that the benefits and burdens of research are distributed fairly



QUESTIONS TO BE ANSWERED IN AN IRB REVIEW

*Are the provisions for protecting privacy
and maintaining confidentiality adequate?*



The Health Insurance Portability & Accountability Act

THE PRIVACY RULE

and

RESEARCH



Several of these slides are abstracted from a presentation

of

Lora Kutkat, NIH Office of Science Policy



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.

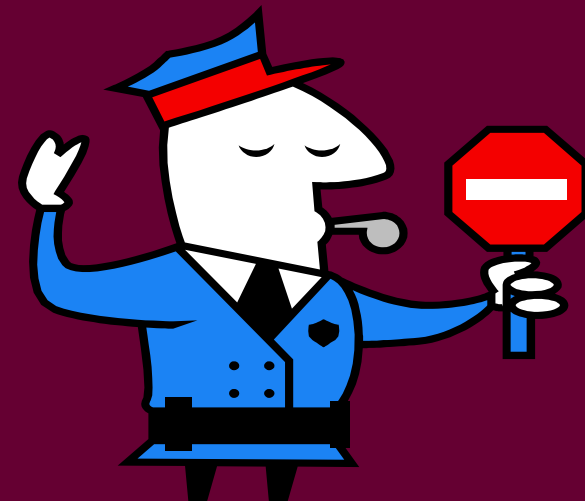


New Concepts Introduced by the Privacy Rule

- An individual's written Authorization is required for use or disclosure of protected health information unless waived or excepted.
- Authorization waivers can be granted by IRBs or Privacy Boards.
- Decedent's information is protected but Authorization is not required.
- Accounting and reporting of disclosures are required.

Privacy Rule, Common Rule, FDA Regulations

- Privacy Rule exceeds privacy protections of Common Rule and FDA regulations.
 - Applies to covered entities regardless of funding
 - Definition of “identifiable information”
 - Requires Authorization for use and disclosure of certain types of health information
 - Applies to decedent’s information



Who is Covered?

- A health care provider who transmits protected health information electronically for any covered HIPAA transaction



What is Covered?

Protected Health Information (PHI)

- Covered Entity + Health information + Identifier = PHI
- Transmitted or maintained in any form (paper, electronic, forms, web-based, etc.)
- Decedents' information included
- Does not include de-identified health information or biological tissue

What is an Identifier in the Privacy Rule?

The Privacy Rule defines 18 identifiers

- Names
- Geographic info (including city, state, and zip)
- **Elements of dates**
- Telephone #s
- Fax #s
- E-mail address
- Social Security #
- **Medical record, prescription #s**
- Health plan beneficiary #s
- Account #s
- Certificate/license #s
- VIN and Serial #s, license plate #s
- Device identifiers, serial #s
- Web URLs
- IP address #s
- Biometric identifiers (finger prints)
- Full face, comparable photo images
- **Unique identifying #s**

Individual Authorizations for Research

- Must be for a specific research study – Authorization for future, unspecified research is NOT permitted but authorization may be used to create a repository or database
- May be combined with informed consent
- Must contain “core elements” & “required statements”
- Research authorizations need not expire



Elements of an Authorization

Authorization to Use and Disclose PHI

Core Elements:

Description of PHI to be used or disclosed

Person(s) authorized to make and receive requested use or disclose

Purpose for the use or disclosure

Expiration date or event* (e.g. “end of the research study” or “none”)

Statements:

Right to revoke
Authorization plus exceptions and process

Ability/Inability to condition treatment, payment, or enrollment/eligibility for benefits on Authorization

PHI may no longer be protected by Privacy Rule once it is disclosed by the covered entity

Patient Signature

Date

***Research authorizations need not expire.**

Research Use and Disclosure of PHI *Without* Authorization

- De-identify PHI
- Limited Data Set with Data Use Agreement
- IRB or Privacy Board waiver of Authorization requirement
- Activity preparatory to research
- Research is on decedent's information
- Research qualifies for the Transition Provisions
- Disclosure to a public health authority or as required by law

Option 1: De-identified Health Information

- Completely de-identified information (18 elements removed) and no knowledge that remaining information can identify the individual. OR
- Statistically “de-identified” information where a statistician certifies that there is a “very small” risk that the information could be used to identify the individual.



Option 2: Limited Data Set with Data Use Agreement

- The Privacy Rule permits limited types of identifiers to be released with health information (referred to as a **Limited Data Set**).
- Limited Data Sets can only be used and released in accordance with a **Data Use Agreement** between the covered entity and the recipient.

Data Use Agreement - REQUIRED

The Data Use Agreement must:

- Describe the permitted uses and disclosures (recipient cannot use or disclose PHI in a way that the covered entity cannot)
- Identify who can use and disclose the PHI
- Require the recipient to:
 - Use or disclose information for specified purposes only
 - Apply safeguards to protect the information
 - Report known violations to the covered entity
 - Hold subcontractors to the same standards as in the agreement
 - Not re-identify the information or contact the individuals

Option 3: Waiver of Authorization

Obtain documentation that an IRB or Privacy Board has determined that each of the following waiver criteria were satisfied.



Authorization Waiver Criteria

IRB/Privacy Board Waiver Checklist

	Yes	No
1. The use or disclosure involves no more than minimal risk because of an adequate plan/assurance:	<input checked="" type="checkbox"/>	<input type="checkbox"/>
a. To protect PHI from improper use or disclosure	<input checked="" type="checkbox"/>	<input type="checkbox"/>
b. To destroy identifiers at earliest opportunity	<input checked="" type="checkbox"/>	<input type="checkbox"/>
c. That PHI will not be inappropriately reused or disclosed	<input checked="" type="checkbox"/>	<input type="checkbox"/>
2. The research could not practicably be conducted without the waiver	<input checked="" type="checkbox"/>	<input type="checkbox"/>
3. The research could not practicably be conducted without access to and use of PHI	<input checked="" type="checkbox"/>	<input type="checkbox"/>

Authorization Waiver Approved

Date

What do IRBs/Privacy Boards review under the Privacy Rule?

- Because the Privacy Rule assumes Authorization will be obtained, IRBs/Privacy Boards will see: Requests to WAIVE Authorization requirement.
- IRBs will see Authorizations that are combined with informed consent documents.

Option 5: Research on Decedents' PHI

Researcher must represent that:

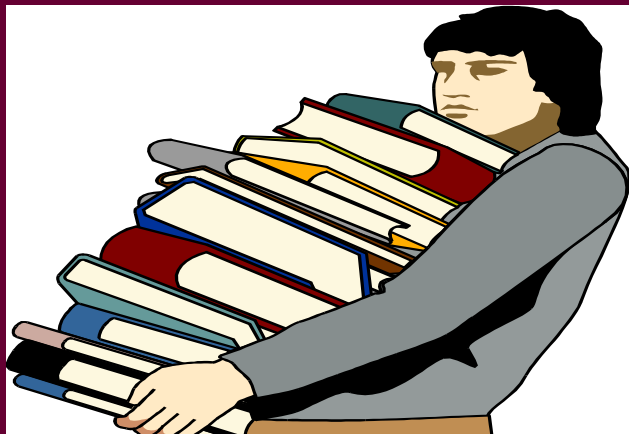
- Use or disclosure solely for research
- PHI is necessary for research, and
- Individual is a decedent, and provide documentation upon covered entity's request.



Privacy Rights Affecting Research

The Privacy Rule generally entitles individuals to:

- Access to their health records
- Receive an accounting of disclosures
- Revoke an Authorization



Access to Research Records

- Individuals have a right to view and copy their health records maintained by covered entities.
- For research records, patients may have right to access records if:
 - The records involve treatment (e.g., some clinical trials) or they are used to “make decisions about individuals.” AND
 - The researcher is a covered entity.
- **EXCEPT:** While a trial is ongoing, covered researchers may deny access if the individual agrees in advance (e.g., in an Authorization).

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.

Stay Tuned for...

- Office for Civil Rights Web site updates

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

- Educational information from NIH and other research agencies

<http://privacyruleandresearch.nih.gov>



▶ Clinical Researchers

Privacy Rule Overview

▶ Health Services Researchers

[Protecting Individual Health Information in Research: Understanding the HIPAA Privacy Rule](#)

▶ Records Researchers

▶ Institutional Review Boards (IRBs)

▶ Privacy Boards

▶ Limited Data Sets & Data Use Agreements

▶ Adverse Event Reporting



Does the Privacy Rule apply to you?

- Navigating the HIPAA Privacy Rule -

▶ Data Sharing

▶ Resources

▶ Glossary

▶ Publication List & Ordering Form

