

# Standards for Privacy of Individually Identifiable Health Information

45 CFR 160 and 164 as amended: August 14, 2002

**HIPAA**

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**April 14, 2003**  
**Implementation Date**

- *Workforce* means employees, volunteers, trainees, and other persons whose conduct, in the performance of work for a covered entity, is under the direct control of such entity, whether or not they are paid by the covered entity

# Compliance and Enforcement

## Complaints to the Secretary

# Right to file a complaint

- A person who believes a covered entity is not complying with the applicable requirements of the part 160 or the applicable standards, requirements and implementation specifications of subpart E of part 164 may file a complaint with the DHHS Secretary.

## Requirements for filing complains

1. A complaint must be filed in writing either on paper or electronically.

2. A complaint must name the entity that is the subject of the complaint and describe the acts or omissions believed to be in violation of the applicable requirements of part 160 or the applicable standards, requirements, and implementation specifications of subpart E of part 164.



3. A complaint must be filed within 180 days of when the complainant knew or should have known that the act or omission complained of occurred, unless this time limit is waived by the DHHS Secretary for good cause shown.

# PART 164

# Security and Privacy

## *Record*

- Any item, collection, or grouping of information that includes protected health information and is maintained, collected, used, or disseminated by or for a covered entity

## *Disclosure*

- The release, transfer, provision of access to, or divulging in any other manner of information outside the entity holding the information.

## *Protected Health Information*

- Means individually identifiable information that is:
  1. Transmitted by electronic media
  2. Maintained in any medium described in the definition of electronic media; or
  3. Transmitted or maintained in any other form or medium.

# *Research*

- A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

# USES AND DISCLOSURES OF PROTECTED HEALTH INFORMATION

## General Rules

## §164.502(a)

- *Standard.* A cover entity may not use or disclose protected health information except as permitted or required.



## Permitted uses and disclosures

1. To the individual
2. For treatment, payment, or health care operations, as permitted by and in compliance with §164.506
3. Incident to use or disclosure otherwise permitted or required
4. Pursuant to and in compliance with an authorization
5. Pursuant to an agreement under, or as otherwise permitted

## Required disclosures

- A covered entity is required to disclose protected health information:
  1. To an individual when requested
  2. When required by the DHHS Secretary

## *Standard:* minimum necessary

- When using or disclosing protected health information or when requesting protected health information from another covered entity, a covered entity must make reasonable efforts to limit protected health information to the minimum necessary to accomplish the intended purpose of the use, disclosure, or request.

*Standard:* uses and disclosures consistent with notice

- A covered entity that is required to have a notice may not use or disclose protected health information in a manner inconsistent with such notice.

## Uses and disclosures for which an authorization is required

- Except as otherwise permitted or required a covered entity may not use or disclose protected health information without an authorization that is valid. When a covered entity obtains or receives a valid authorization for its use or disclosure of protected health information, such use or disclosure must be consistent with such authorization.

# AUTHORIZATION

## Core Elements

1. A description of the information to be used or disclosed that identifies the information in a specific and meaningful fashion.

2. The name or other specific identification of the person(s), or class of persons, authorized to make the requested use or disclosure.



3. The name or other specific identification of the person(s), or class of persons, to whom the covered entity may make the requested use or disclosure.

4. A description of each purpose of the requested use or disclosure. The statement “at the request of the individual” is a sufficient description of the purpose when an individual initiates the authorization and does not, or elect not to, provide a statement of the purpose.

5. An expiration date or an expiration event that relates to the individual or the purpose of the use or disclosure. The statement “end of the research study”, “none”, or similar language is sufficient if the authorization is for a use or disclosure of protected health information for research, including the creation and maintenance of a research database or research repository.

6. Signature of the individual and date. If the authorization is signed by a personal representative of the individual, a description of such representative's authority to act for the individual must be provided.

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# AUTHORIZATION

## Required Statements

1. The individual's right to revoke the authorization in writing
2. The ability or inability to condition treatment, payment, enrollment or eligibility for benefits
3. The potential for information disclosed pursuant to the authorization to be subject to redisclosure by the recipient and no longer be protected

- The authorization must be written in plain language.
- If a covered entity seeks an authorization from an individual for a use or disclosure of protected health information, the covered entity must provide the individual with a copy of the signed authorization.

## *Standard:* use and disclosure for research purposes

- A covered entity may use and disclose protected health information for research, regardless of the source of funding of the research.



## Board approval of a waiver of authorization

- The covered entity must obtain documentation that an alteration to or waiver, in whole or in part, of the individual authorization required for use or disclosure of protected health information has been approved by either:
  - An Institutional Review Board; or
  - A Privacy Board

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# Institutional Privacy Board

## *Membership*

1. The Privacy Board has members with varying backgrounds and appropriate professional competency as necessary to review the effect of the research protocol on the individual's privacy rights and related interests.

2. Includes at least one member who is not affiliated with the covered entity conducting or sponsoring the research, and not related to any person who is affiliated with any of such entities.

3. Does not have any member participating in a review of any project in which the member has a conflict of interest.

# WAIVER CRITERIA

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

1. An adequate plan to protect the identifiers from improper use and disclosure;



2. 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

3. 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 study, or for other research for which the use or disclosure of protected health information would be permitted.

- The research could not practicably be conducted without the waiver or alteration

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

## Documentation of waiver approval

1. Identification and date of action
2. Waiver criteria
3. Protected health information needed
4. Review and approval procedures
5. Required signature

# Identifiers

- Names
- All geographic subdivisions smaller than a State, including street address, city, country, precinct, zip code, and their equivalent geocodes
- All elements of dates (except year)

- Telephone numbers
- Fax numbers
- Electronic mail addresses
- Social security numbers
- Medical record numbers
- Health plan beneficiary numbers
- Account numbers

- Certificate/license numbers
- Vehicle identifiers and serial numbers, including license plate numbers
- Device identifiers and serial numbers
- Web Universal Resource Locators (URLs)
- Internet Protocol (IP) address numbers



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<http://committees.rcm.upr.edu>