

The Impact of The HIPAA Privacy Rule on Research



This is simplification?

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WHAT HASN'T CHANGED

- All research involving human subjects must be reviewed and approved by the IRB.
- The common rule (45 CFR 46) is still our guide.

The Privacy Rule

Protects the privacy of individually identifiable health information by establishing conditions for its use and disclosure.

- When/If the regs conflict, the one with the highest privacy protection for the subject wins.

The Privacy Rule & Research

The Privacy rule adds an additional layer of protection and regulations to human subject research.

HIPAA SPEAK



1. Individually Identifiable Health Information (IIHI)

Health information + Identifiers (18 defined) = **IIHI**

2. De-identified information

Health Information – Identifiers (all 18) = **De-identified**

3. Use (of IIHI)

Sharing within the entity. For example, when members of the covered entity's workforce share IIHI.

4. Disclosure (of IIHI)

Sharing outside the entity. For example, sharing IIHI with someone who is not a member of the covered entity's workforce.

What Are The 18 Identifiers?

1. Name- including initials (of the individual, relatives, employer, etc.)
2. Address (street, town or city, state, and zip)
3. Telephone numbers
4. Fax numbers
5. Social security numbers
6. Dates related to an individual, except for years (birth date, admission date, date of death, ages > 89 and all elements of dates indicative of such age).
7. Electronic mail (e-mail) addresses
8. Web universal resource locators (URLs)
9. Internet protocol (IP) address #s
10. Medical record numbers
11. Health plan beneficiary numbers
12. Account numbers
13. Certificate/license numbers
14. Vehicle identifiers and Serial numbers (e.g., VINs, license plate numbers)
15. Medical device identifiers and serial numbers.
16. Biometric identifiers (e.g., finger or voice prints)
17. Full face photographic images (and any comparable images)
18. Any other unique identifying number, characteristic, or code*

HIPAA SPEAK

- **The Minimum Necessary Standard**

Uses and disclosures of IIHI must be limited to the Minimum Necessary to achieve the research purpose.

- The minimum necessary requirement is applicable in certain situations.

HIPAA SPEAK

- **Accounting For Disclosures**
 - A covered entity is generally required to account for disclosures of PHI made without Authorization.
- The accounting requirement also includes:
 - Disclosures to public health authorities
 - Most disclosures mandated by law.

What Research Is Subject to The Privacy Rule?

- All human subject research which involves the use of IIHI.

- Decedent's IIHI

What Research Is Not Subject to The Privacy Rule?

- **De-identified** health information.
- **Biological specimens** (may apply to associated information).

The Impact of the Privacy Rule on Research

The Privacy Rule permits covered entities to use and disclose IIHI for research under the following conditions:

1. With individual authorization,

or

2. Without individual authorization- **under certain limited circumstances.**

Using and/or disclosing IIHI WITH Authorization @ Upstate

- Authorization is combined with the informed consent document.
- Must contain required information & statements.
- Must be for a specific research study – blanket Authorization NOT permitted.
 - Requests to bank AND use data/specimens for future unknown research will not be allowed. You can only ask permission to bank.
- No expiration date for the authorization is required.

Retention of Signed Authorization

- Signed authorizations must be retained for six years from the date signed or from the date when last in effect, whichever is later.
- If there is no specific expiration date, the authorization form should be kept indefinitely.

Additional Requirements when Obtaining Consent/Authorization

- Research subjects must be given a copy of the Notice of Privacy Practices (NOPP) when consent/authorization is obtained.
- The researcher must provide the subject with a signed copy of the consent/authorization document.

Using and/or disclosing IIHI WITH Authorization

- **If you obtain authorization:**
 - The Minimum Necessary Requirement does not apply.
 - The Accounting for Disclosures Requirement does not apply (if consent/authorization form is correct).

Options for using and/or disclosing IIHI WITHOUT Authorization

1. De-identification.
2. Limited Data Set with Data Use Agreement.
3. Waiver of Authorization.

De-identification

- ❑ The Privacy Rule does not apply to de-identified health information.
- ❑ The Privacy Rule does not apply to coded health information.

To de-identify:

1. Remove all 18 defined identifiers and no knowledge that remaining information can identify the individual.
2. 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.

De-identification

3. Code information- may assign a code or other means of record identification to allow information to be re-identified provided that:
 - i. The code or other means of record identification is not derived from or related to information about the individual and is not otherwise capable of being translated so as to identify the individual; and
 - ii. The code is not used or disclosed for any other purpose and the mechanism for re-identification is not disclosed.

NOTE:

Even though the Privacy Rule does not apply to such coded information, the common rule considers coded information to be indirectly identifiable. Therefore, even if a researcher de-identifies information via coding, a protocol should be submitted to the IRB.

Options for using and/or disclosing IIHI WITHOUT Authorization

1. **De-identification.**
2. Limited Data Set with Data Use Agreement.
3. Waiver of Authorization.

Limited Data Set

- **A set of data which is not fully de-identified**

To use a limited data set, a Data Use Agreement (DUA) must first be in place with the recipient of the information (can be researcher or outside entity, e.g., registry).

Identifiers which may be used and disclosed with a Limited Data Set

1. Names (any, and all elements of)
2. Address (street, town or city, state, and zip)
3. Telephone numbers
4. Fax numbers
5. Social security numbers
6. Dates related to an individual, except for years (birth date, admission date, date of death, ages > 89 and all elements of dates indicative of such age).
7. Electronic mail (e-mail) addresses
8. Web universal resource locators (URLs)
9. Internet protocol (IP) address numbers
10. Medical record numbers
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18. Any other unique identifying number, characteristic, or code.

Data Use Agreement

- The Data Use Agreement defines the permissible uses/disclosures of the LDS by the recipient, defines who can use or receive the data, and requires the recipient to assure that data will not be re-identified and that individuals will not be contacted.

Limited Data Set

- **If you use a Limited Data Set:**
 - The Minimum Necessary Requirement does apply.
 - The Accounting for Disclosures Requirement does not apply.

Options for using and/or disclosing IIHI WITHOUT Authorization

1. **De-identification.**
2. Limited Data Set with Data Use Agreement.
3. Waiver of Authorization.

Waiver of authorization

The IRB can waive the requirement to obtain authorization for use or disclosure of IIHI if the following criteria are met:

1. The use and/or disclosure of IIHI for the research involves no more than minimal risk to the privacy of individuals, based on:

- an adequate plan to protect identifiers from improper use
- an adequate plan to destroy identifiers at the earliest opportunity, and
- adequate written assurances that health information will be protected

2. The research could not practicably be conducted without the waiver or alteration; and

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

Waiver of authorization

- **If you have a waiver:**
 - The Minimum Necessary Requirement applies.
 - The Accounting for Disclosures Requirement applies.

Accounting for Disclosures

- **The researcher must record for each disclosure:**
 - List of individuals.
 - Date of disclosure.
 - Name of person/entity to whom the disclosure was made (including their address, if known).
 - Description of the IIHI disclosed.
 - Statement regarding the purpose for the disclosure.

Accounting for Disclosures Modified Tracking

- For research involving the disclosure of IIHI from 50 or more subjects - modified tracking allowed.

**Do not have to maintain a list of
specific individuals.**

Accounting for Disclosures Modified Tracking

- **The researcher must report to the Privacy Officer:**
 - Name of the protocol or research activity.
 - Description (in plain language) of the research protocol/ activity, purpose of the research, and criteria for selecting particular records.
 - A description of the type of IIHI disclosed.
 - Date or time period during which the disclosure(s) occurred, including the date of the last disclosure.
 - Contact information (name address and phone number) of the research sponsor and the recipient of the IIHI.

Research on Decedent's

Not required to obtain **authorization** (from next of kin), **waiver of authorization** (from an IRB), or **data use agreement**.

- The researcher must provide written representation that:
 - the use/disclosure is sought solely for research on the IIHI of decedents,
 - The IIHI requested for the use/disclosure is necessary for the research purposes, AND
- At the request of the covered entity, the researcher must provide documentation of the death of the individuals whose IIHI is sought.

Research on Decedent's

- The Minimum Necessary Requirement applies.
- The Accounting for Disclosures Requirement applies.

Studies which are exempt from IRB review under the Common Rule

- The IRB will continue to screen studies for which an exemption from IRB review is requested.
- The IRB will continue to issue exemption letters, which confirm that studies meet the criteria for exemption under the common rule **and comply with the Privacy Rule.**

Requesting an exemption from IRB review for Chart Review or Specimen Research Studies

In order to be eligible for an exemption from IRB review, the research must be retrospective and anonymous.

1. Submit a letter, signed by a faculty member, requesting an exemption from IRB review to the IRB office, which briefly describes the project and includes the following information:

- The dates of records/specimens to be reviewed (to establish that the study is retrospective).

2. Attach a completed *de-identification form* (IRB web site) to establish that the study is anonymous and to certify that the de-identification will only be done by Upstate faculty, staff or students.

Access to IIHI to Prepare a Research Proposal

- Members of the Upstate workforce (faculty, staff & students) may access IIHI, without authorization, provided that:
- The IIHI is to be used solely to prepare a research protocol or for a similar purpose
- The IIHI will not be removed from the covered entity
- The IIHI is necessary for the research purposes.

Access to IIHI to Prepare a Research Proposal

- The Minimum Necessary Requirement applies.
- The Accounting for Disclosures Requirement applies.

Access to individually identifiable health information for research

Access to IIHI for research will be possible via one of the acceptable routes:

- ✓ **authorization**
- ✓ **waiver of authorization**
- ✓ **de-identification**
- ✓ **limited data set**

Access to individually identifiable health information for recruitment purposes

- Most currently approved plans for recruiting research subjects will be in compliance with the Privacy rule.

Common Rule

Institutional Review Board

Privacy

Rule

1. Choose an Entree



EXEMPT

FULL BOARD

EXPEDITED

2. Choice must be based on criteria outlined in the common rule (45CFR 46).

IRB Review is based on the ethical principles (respect, beneficence, justice)

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3. Pick an appropriate wine to complement your entree



AUTHORIZATION



WAIVER



DE-IDENTIFICATION



LIMITED DATA SET

IRB functions:

- Review all human subjects research.
- Review combined consent/authorization forms.
- Review exemptions using de-identified data (or LDS's when appropriate).
- Review requests for waivers of authorization.

Privacy Board

functions:

- Review requests for access to IIHI for reviews preparatory to research.
- Review requests for access to decedent's IIHI for research.
- Execute data use agreements.