

Health Insurance Portability and Accountability Act (HIPAA)

Scope

Mayo Clinic Human Research Protection Program

Research for which the Mayo Clinic is the IRB of Record

Purpose

Under the Federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) Security and Privacy Rule, researchers must meet certain requirements before using or disclosing individually identifiable health information for research. The purpose of this policy is to describe confidential protections required when Protected Health Information is used for research purposes.

Policy

Privacy Board

The Mayo Clinic IRB serves as the Privacy Board for research conducted at Mayo Clinic and external sites, as applicable, and may grant approval of authorization documentation or waive the requirement of HIPAA authorization as Federal regulations allow.

Protected Health Information and HIPAA

The HIPAA Privacy Rule defines "individually identifiable" information broadly, to include information such as name, address, or SSN, as well as "indirect identifiers" such as zip codes or date of birth, when attached to any health information.

A covered entity and its employees may not use or disclose individually identifiable health information (called "protected health information", or "PHI") for research, except in one of the following circumstances:

- The patient/participant has signed a written authorization containing all the elements specified in the Privacy Rule, or
- An IRB has waived or altered the requirement for HIPAA authorization, or
- The covered entity and its employees have "de-identified" the data prior to its use and disclosure for research, or
- The data are in the form of a "limited data set" and the investigator/recipient of the data has signed a data use agreement

Research Use or Disclosure of PHI with Authorization

A legally effective authorization includes the following elements:

- A description of the information to be used or disclosed that identifies the information in a specific and meaningful way
- The name or other specific identification of the person(s), or class of persons, authorized to make the requested use of disclosure
- The name or other specific identification of the person(s), or class of persons, to whom the Investigators may make the requested use or disclosure
- A description of each purpose of the requested use or disclosure

- An expiration date or an expiration event that relates to the individual or the purpose of the use or disclosure. The statement such as "end of research study" or "none" may be used when appropriate
- A statement that the individual may revoke the authorization if requested in writing. However, the Investigator may continue to use and disclose, for research integrity and reporting purposes, any PHI collected from the individual pursuant to such authorization before it was revoked
- A statement that either: the institution may not condition treatment, payment or eligibility for benefits on whether the individual signs the authorization (for non-treatment studies) or the institution may condition the individual's research-related treatment on the provision of the authorization (for treatment studies)
- A statement that information disclosed pursuant to the authorization could potentially be subject to re-disclosure by the recipient and no longer be protected under HIPAA and
- The individual's signature (or that of his/her legally authorized representative) and date.

An authorization for the use or disclosure of PHI for a research study may be combined with any other type of written permission for the same research study (including the consent form).

A signed copy of an authorization for the use or disclosure of PHI may be received by facsimile or electronically transmitted.

Research Use or Disclosure of PHI with Waiver of Authorization

Authorizations may be waived or altered by the IRB, provided the following criteria are satisfied and documented:

1. The use or disclosure of PHI involves no more than minimal risk to the privacy of individuals, based on the presence of at least the following elements:
 - An adequate plan to protect the identifiers from improper use and disclosure
 - An adequate plan to destroy the identifiers at the earliest opportunity consistent with the conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law and
 - Adequate written assurances that the PHI 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 PHI would be permitted by this policy.
2. The research could not practicably be conducted without the waiver or alteration.
3. The research could not practicably be conducted without access to and use of the PHI.

When uses or disclosures of PHI are made pursuant to a waiver, the Investigator must make reasonable efforts to limit PHI to the minimum necessary to accomplish the intended purpose of the use or disclosure.

Research Use or Disclosure of a Limited Data Set

An investigator may use or disclose a Limited Data Set for research purposes without an authorization or waiver of authorization, if a Data Use Agreement is completed. For example, a Data Use Agreement is used when an investigator wants to share a Limited Data Set of research data with a colleague at another institution or with a private registry not involved in the study.

When uses or disclosures of a Limited Data Set are made pursuant to a Data Use Agreement, the investigator must make reasonable efforts to limit PHI to the minimum necessary to accomplish the intended purpose of the use or disclosure.

A Limited Data Set excludes direct identifiers of the individual or of relatives, employers, or household members of the individual as defined in the De-identification of Protected Health Information and Limited Data Set Policy. A Limited Data Set may include:

- Study identification number, subject ID, or any other unique identifying number, characteristic, or code related to or derived from an existing direct identifier.
- Dates: all elements of dates [month, day, and year] directly related to an individual, e.g. date of birth, death, or diagnosis, etc.
- City, county, precinct, zip code, and their equivalent geocodes

Research Use or Disclosure of Decedent's PHI without Authorization

An investigator may use and disclose a decedent's PHI for research purposes without IRB review provided that all of the following criteria are satisfied:

- The use or disclosure is solely for research on the PHI of decedents,
- The PHI for which use or disclosure is sought is necessary for research purposes, and
- The Investigator has documentation of the death of the individuals whose PHI is being sought.

For PHI that is included in medical records at Mayo Clinic Rochester or any institution in Minnesota, an investigator may use and disclose a decedent's PHI for research purposes in accordance with Minnesota Research Authorization. After an individual's death, the individual's Minnesota Research Authorization status continues to apply and cannot be changed by a relative or other authorized representative.

When uses or disclosures of a decedent's PHI are made without HIPAA authorization, the investigator must make reasonable efforts to limit PHI to the minimum necessary to accomplish the intended purpose of the use or disclosure.

Research Use or Disclosure of "De-Identified" Health Information

De-identified health information is exempt from HIPAA regulations and may be used or disclosed for research purposes without an authorization or IRB waiver of authorization.

De-identified health information is health information that has been stripped of all 18 direct identifiers as defined by the [De-identification of Protected Health Information and Limited Data Set Policy](#).

De-identified information may be assigned a code or other means of record identification to allow de-identified information to be re-identified, provided that the key to such a code is not accessible to the investigator requesting to use or disclose the de-identified health information, the code is not derived from or related to information about

the individual, and the code is not capable of being translated so as to identify the individual.

Use of PHI that is Reviewed Preparatory to Research

An investigator may use PHI (Protected Health Information) without IRB review for activities considered preparatory to research if all of the following criteria are satisfied:

- Use is sought solely to review PHI as necessary to design a research study, assess the feasibility of conducting a study, or identify prospective research participants, for purposes preparatory to research,
- No PHI is to be removed from or disclosed external to the covered entity by the investigator in the course of the review,
- The PHI for which use is sought is necessary for the research purposes, and
- Mayo Clinic investigators have submitted a Review Preparatory to Research form located on the IRB website.

When accessing PHI for activities preparatory to research, the investigator must make reasonable efforts to limit use and recording of PHI to the minimum necessary to accomplish the intended purpose of the use.

IRB approval is required prior to the analysis of the PHI abstracted from Review Preparatory to Research activities. If there is not an IRB approved protocol submitted following the Review Preparatory to Research, then the abstracted data cannot be analyzed or disseminated in any form.

Participant's Access to Research Information

An individual who participates in research generally has a right to access his/her own PHI that is maintained in a Designated Record Set. However, an individual's access to PHI created or obtained in the course of research that involves treatment may be temporarily suspended for as long as the research is in progress, provided that the individual has agreed to the denial of access when consenting to participate in the research study, and the investigator has informed the individual that the right of access is to be reinstated upon completion of the research.

Participant's Request to Revoke Research Authorization

An individual may revoke his or her authorization at any time, provided that the revocation is in writing, except to the extent that the investigator has taken action in reliance on the authorization. The investigator may continue to use and disclose any PHI collected pursuant to a valid authorization before it was revoked, for study integrity and reporting purposes.

HIPAA Authorization and Informed Consent

Informed consent is required under federal research regulations for the protection of human subjects. The HIPAA Privacy Rule requires that patients give written authorization before a covered entity may use or disclose patients' protected health information for research.

There are different requirements for the content of informed consent and HIPAA authorization. Under the federal privacy regulations, an institution may combine the informed consent and HIPAA authorization in the following circumstances:

1. If the authorization is for use or disclosure of PHI for research-related treatment, the institution may combine the consent to participate in the study with the authorization to use or disclose the PHI for that study.
2. The authorization combines provisions where the institution is allowed to condition the provision of treatment on the individual's agreement and other provisions where the institution may not condition the provision of treatment on the individual's agreement. The authorization must allow the individual to opt-in to the unconditioned authorization. The authorization will clearly state that the individual may choose not to opt-in to the unconditioned option and this choice will not impact the provision of treatment. For example, research subjects/patients may sign an authorization for use or disclosure of their PHI in order to receive the research-related treatment (a "conditioned authorization"), and they are free to opt-in to a tissue and data banking authorization ("unconditioned authorization"). The institution may not condition the provision of research-related treatment on opting-in to the tissue banking option.

The IRB may waive both consent and authorization if the research meets all of the waiver criteria established by each of the applicable regulations.

Related Procedure(s)

N/A

Related Document(s)

Authorization to Use and Disclose Protected Health Information form

<http://intranet.mayo.edu/charlie/irb/child-of-page-1/forms-library/>

De-identification of PHI and Limited Data Set Policy

<http://mayocontent.mayo.edu/prmr/DOCMAN-0000158670>

Minnesota Research Authorization

<http://intranet.mayo.edu/charlie/irb/home/minnesota-research-authorization/>

Submission Form for Reviews Preparatory to Research

<http://intranet.mayo.edu/charlie/irb/home/review-preparatory-to-research-rpr/>Valid

Authorization Requirements for PHI Policy

<http://mayocontent.mayo.edu/prmr/DOCMAN-0000167276>

Definitions

Covered Entity: HIPAA regulations apply to health plans, health care clearinghouses and health care providers who transmit health information. Any individual creating or accessing Protected Health Information (PHI) for the delivery of healthcare at Mayo Clinic is within the covered entity.

De-identified Protected Health Information: Information that is no longer individually identifiable and cannot be used, alone or in combination with other reasonably available information, to identify the individual, i.e. all direct identifiers have been removed.

Designated Record Set: A group of records maintained by or for Mayo Clinic that is:

The medical records and billing records about individuals maintained by or for Mayo Clinic;

The enrollment, payment, claims adjudication, and case or medical management record systems maintained by or for a Mayo Clinic health plan; or

Used, in whole or in part, by or for Mayo Clinic to make decisions about individuals.

For purposes of the above paragraph, the term record means any item, collection, or grouping of information that includes protected health information and is maintained, collected, used, or disseminated by or for Mayo Clinic.

Direct Identifiers:

1. Names
2. Geographic subdivisions smaller than a state (except the first three digits of a zip code if the geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people and the initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000)
3. All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, and date of death and all ages over 89 and all elements of dates (including year) indicative of such age
4. Telephone numbers
5. Fax numbers
6. Electronic mail addresses
7. Social security numbers
8. Medical record numbers
9. Health plan beneficiary numbers
10. Account numbers
11. Certificate/license numbers
12. Vehicle identifiers and serial numbers, including license plate numbers
13. Device identifiers and serial numbers
14. Web Universal Resource Locators (URLs)
15. Internet Protocol (IP) address numbers
16. Biometric identifiers, including finger and voice prints
17. Full face photographic images and any comparable images
18. Any other unique identifying number, characteristic, or code (excluding a random identifier code for the subject that is not related to or derived from any existing direct identifier)

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

Limited Data Set: Set of data that may be used for research, public health, or health care operations without an authorization or waiver of authorization. A limited data set excludes specified direct identifiers of the individual or of relatives, employers, or household members of the individual, as defined by the [De-identification of Protected Health Information and Limited Data Set Policy](#)

Protected Health Information (PHI): Individually identifiable health information held or transmitted in any form or medium, including information created or received by a health care provider, health plan, employer or health care clearinghouse that relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present or future payment for the provision of health care to an individual; and that identifies the individual or for which there is a reasonable basis for believing that the information could be used to identify the individual. PHI includes medical, scheduling, and billing information.

References

45 CFR Part 164 - Security and Privacy Rule, Subpart E- HIPAA Privacy and Research

<http://www.hhs.gov/ocr/privacy/hipaa/understanding/special/research/>

De-identification of Protected Health Information and Limited Data Set Policy

<http://mayocontent.mayo.edu/prmr/DOCMAN-0000158670>

Approved by

Pamela Kwon on behalf of the Office for Human Research Protections 10/26/2016

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Revision History

Date	Synopsis of Change
1/23/2017	Minor revision. Updated the following definitions per Glossary review: Covered Entity, and Direct Identifiers. Added: Direct Identifiers.
10/26/2016	Synopsis of changes: Based on feedback from study teams and IRB staff: Editorial changes for clarity, added definition of Designated Record Set, linked to De-identification of Protected Health Information and Limited Data Set Policy