Health Insurance Portability and Accountability Act (HIPAA) Policy

Content Applies To

Mayo Clinic Human Research Protection Program

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.

Privacy Board

The Mayo Clinic IRB serves as the Privacy Board (HIPAA) for research conducted at Mayo Clinic 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 do 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" containing no HIPAA "direct identifiers," and the investigator 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: Mayo Clinic may not condition treatment, payment or eligibility for benefits on whether the individual signs the authorization (for non-treatment studies) or Mayo Clinic 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 is 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 PHI with Waiver of Authorization Outside of Mayo Clinic

If the IRB grants a waiver and the Investigator discloses any PHI outside Mayo Clinic, the Investigator must record the following information for any PHI disclosed and report this to the IRB as a Reportable Event:

- The date of the disclosure
- The name of the entity or person who received the PHI and, if known, the address of such entity or person
- A brief description of the PHI disclosed and
- A brief statement of the purpose of the disclosure that describes the basis for disclosure.

Research Use or Disclosure of 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 not involved in the clinical trial, 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 is PHI that excludes direct identifiers of the individual or of relatives, employers, or household members of the individual, with the exception of city, state, ZIP code, all elements of dates and other numbers, characteristics, or codes not listed as direct identifiers.

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 facility 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 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 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 identifiers as defined by HIPAA so that the information could not be traced back to an individual.

De-identified information may be assigned code or other means or 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 and the code is not derived from or related to information about the individual and 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 Mayo Clinic by the investigator in the course of the review,
- The PHI for which use is sought is necessary for the research purposes, and
- The investigator has 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 data abstracted from Review Preparatory to Research activities. If there is not an IRB approved protocol submitted post Review Preparatory to Research, then the abstracted data cannot be analyzed or disseminated in any form.

Participant's Access to Research Information

Individuals who participate in research generally have 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 [Mayo Clinic] may use or disclose patients' protected health information for research. There are different requirements for the content of informed consent and HIPAA authorization; however both may be combined

in one form. 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 Documents

Authorization to Use and Disclose Protected Health Information form

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

Submission Form for Reviews Preparatory to Research

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

Minnesota Research Authorization

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

References

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