

|  |  |
| --- | --- |
| Policy | P.19 |
| Written By: | B. Laurel Elder |
| Created: | 3/6/12 |
| Edited |  7/22/14 |
| Version | P.19.2 |

**Using Protected Health Information In Research**

**Introduction**:

The **Health Insurance Portability and Accountability Act of 1996 (HIPAA)** contains provisions to protect the confidentiality and security of personally-identifiable information that arises in the course of providing health care. In order to understand how HIPAA affects research, there are a few important terms that are defined by the law.

The HIPAA Privacy Rule governs **Protected Health Information (PHI)** which is defined as information that can be linked to a particular person (ie., is person-identifiable) that arises in the course of providing a health care service.

When PHI is communicated inside of a covered entity (such as a hospital or health care facility), this is called a **use** of the information. When PHI is communicated to another person or organization that is not part of the covered entity, this is called a **disclosure**. HIPAA allows both use and disclosure of PHI for research purposes, but such uses and disclosures have to follow HIPAA guidance and have to be part of a research plan that is reviewed and approved by an Institutional Review Board (IRB).

**Definitions:**

**Authorization:** Under HIPAA, the granting of rights to access PHI. Authorization is required by HIPAA for disclosures or uses other than for Treatment Procedures Operations (TPO), which are covered in the Notice of Privacy Practices. Treatment cannot be conditioned on granting of an authorization. An authorization is a specific, detailed document requesting patient-subject permission for the use of covered PHI.

**Covered Entity:** A covered entity is a health plan, a health care clearinghouse, or a health care provider transmitting health information, and is, therefore, subject to the HIPAA regulations.

**Disclosure:** The release, transfer, provision of access to, or divulging in any other manner of PHI outside the entity holding the information. Disclosure of PHI requires a specific authorization under HIPAA except if disclosure is related to the provision of TPO (Treatment Procedures Operations) of the entity responsible for the PHI or under a limited set of other circumstances, such as public health purposes.

**Health Information:** Any information, whether oral or recorded in any form or medium, that:

* Is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse; and
* 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.

**Hybrid Entity:** A single legal covered entity with health care and non-health care functions, where the former are covered functions but are not its primary functions. The University of California is a hybrid entity.

**Individually Identifiable Health Information** is any information created, used, or received by a health care provider that relates to:

* The past, present, or future physical or mental heath 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 with respect to which there is a reasonable basis to believe the information can be used to identify the individual. The collection of individually-identifiable health information for research constitutes human subjects research.

**Minimum Necessary Standard:** The least information reasonably necessary to accomplish the intended purpose of the use, disclosure, or request of PHI.

**Notice of Privacy Practices:** The HIPAA Privacy Rule gives individuals a fundamental right to be informed of the privacy practices of their health plans and of most of their health care providers, as well as to be informed of their privacy rights with respect to their personal health information. Health plans and covered health care providers are required to develop and distribute a notice that provides clear explanations of these rights and practices. The Notice of Privacy Practices is intended to focus individual on privacy issues and concerns, and to prompt them to have discussions with their health plans and health care providers and exercise their rights. Note: Sometimes the Notice of Privacy Practices is interchangeable with PHI.

**Personal Health Information** is used on the University of California HIPAA Authorization form in order to (1) capture the meaning of both protected health information (*HIPAA* term) and medical information (*California Health & Safety Code: California Confidentiality of Medical Information* term),  (2) communicate to the research subject that information is "personal", and (3) convey information at an eighth-grade reading level.

**Protected Health Information (PHI)** is defined as any individually identifiable health information collected or created as a consequence of the provision of health care by a covered entity, in any form, including verbal communications.

**Research That is Covered by HIPAA**

HIPAA affects only that *research which uses, creates, or discloses Protected Health Information* (PHI). In general, there are two ways a research study would involve PHI:

* The study involves review of medical records as one (or the only) source of research information. Retrospective studies involve PHI in this way. Prospective studies may do this also, such as when a researcher contacts a participant's physician to obtain or verify some aspect of a person's health history.
* The study creates new medical records because as part of the research a health-care service is being performed, such as testing of a new way of diagnosing a health condition or a new drug or device for treating a health condition.

Most sponsored clinical trials that submit data to the US Food and Drug Administration (FDA) will involve PHI because study monitors have an obligation to compare research records such as Case Report Forms (CRFs) to the medical records of the persons participating in the study, in order to verify that the information transcribed onto the CRFs is accurate.

Human biological specimen data which includes PHI is also considered clinical research.

**Protected Health Information Under HIPAA**

HIPAA recognizes that health-related information is often so rich in content that it can never be made truly anonymous, but that the risk of re-identification of an individual is greatly decreased by removing certain elements from data. Health information lacking these elements is said to be ***de-identified*** and may be used or disclosed without restriction under the HIPAA Privacy Rule (the health information is no longer PHI).

To de-identify PHI, remove the following ***list of 18******identifiers*** of the individual and of the individual.s relatives, employers, or household members:

1. ***Names***
2. ***All geographic subdivisions smaller than a state***, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code if, according to the current publicly available data from the Bureau of the Census: (1) the geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and (2) 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, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older.
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***

**Use and Disclosure of PHI for Research**

HIPAA permits the use or disclosure of PHI for research under the following circumstances and conditions:

* If the subject of the PHI has granted specific written permission through an ***Authorization***. This authorization may be a separate consent form signed by the subject, or may be included in the research consent form (see next section).
* If the IRB has granted a ***waiver of the authorization*** requirement
* If the ***PHI has been de-identified*** in accordance with the standards set by HIPAA

***Getting Authorization to Use PHI***

The principle of respect for persons means that, if it is feasible to get the consent of someone before using their PHI for research, then consent should be obtained. HIPAA refers to consent for use of information as an Authorization, and requires that the following elements be present in an Authorization to use PHI for research purposes:

1. A description of information to be used or released,
2. The name of person(s) or class of persons (e.g., project staff) who will use the information,
3. The name of persons or organizations to whom PHI will be released. (e.g., central coordinating offices of multi-center trials),
4. The expiration date or event that ends authorization to use PHI (e.g., completion of the research), or statement that authorization does not expire,
5. A statement that the research participant has the right to revoke authorization (as part of withdrawal from study procedures),
6. A statement that if information will be disclosed to other organizations the information may no longer be protected, and
7. A statement that individuals may inspect or copy their records. The researcher may stipulate that records will not be available until after the study is complete.

**Waiver of HIPAA Authorization**

For certain research (most commonly chart reviews) HIPAA authorization by the subject is not feasible and a waiver of the HIPAA authorization may be requested.

To request a waiver, the PI must fill out the petition, providing complete responses to all questions.

The study reviewer will document all responses on the reviewer checklist, indicating if approval has been granted for the waiver.

For studies originating at the VA, an additional form must be filled out an filed with the study indicating that the study has been reviewed and approved by the authorized VA IRB member. This is done at the VA, most commonly as part of the Research and Development committee review of the research.

***Getting Authorization to Use PHI***

The principle of respect for persons means that, if it is feasible to get the consent of someone before using their PHI for research, then consent should be obtained. HIPAA refers to consent for use of information as an Authorization, and requires that the following elements be present in an Authorization to use PHI for research purposes:

1. A description of information to be used or released,
2. The name of person(s) or class of persons (e.g., project staff) who will use the information,
3. The name of persons or organizations to whom PHI will be released. (e.g., central coordinating offices of multi-center trials),