

## Using Patient Data for Research under HIPAA

The HIPAA Privacy Rule outlines the conditions under which health care data may lawfully be used for research purposes. Effective April 14, 2003, any use for new studies must meet one of two conditions:

1. Permission is granted by the patient, through a written authorization form

OR

2. One of the following criteria is met:
  - a) the information is completely de-identified and no longer governed by HIPAA
  - b) the information is compiled into a “limited data set” and a data use agreement is executed
  - c) the activity qualifies as “preparatory to research”
  - d) a waiver of the individual authorization requirement is obtained from an institutional review board (IRB) or privacy board
  - e) the researcher is accessing information solely on decedents

*Note: Certain previously-approved studies that continue after 4/14/03 may have an authorization requirement. See below under “Transition Requirements.”*

### Written Authorization

Written authorization from the patient is the default requirement for use of protected health information in research. Prospective research, such as a clinical trial, generally requires prior authorization. When written authorization is required, the authorization form must contain the following elements:

- A specific description of the protected health information to be used or disclosed
- The names or classes of individuals authorized to make the use or disclosure
- The names or classes of individuals authorized to receive the use or disclosure
- Description of each purpose of the requested use or disclosure. Specific purposes must be listed; no “blanket” authorization is permitted.
- An expiration date or event for the authorization
- A statement that the individual has a right to revoke the authorization
- A reference to the covered entity’s right to condition service on the authorization, or the consequences of refusal to sign.
- A statement that the information used or disclosed pursuant to the authorization may be subject to re-disclosure by the recipient and no longer protected by the Privacy Rule.

Accounting requirements: Research disclosures made under a written authorization are excluded from the “accounting of disclosures” requirement, since patients become aware of the disclosure by signing the authorization form.

## De-identification

Certain research projects can be accomplished through the use of de-identified data. De-identified data is not subject to HIPAA regulations. To qualify as being de-identified under the Privacy Rule, the following data elements about the individual *and the individual's relatives, employers, or household members* must be removed:

- (A) Names;
- (B) 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;
- (C) 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;
- (D) Telephone numbers;
- (E) Fax numbers;
- (F) Electronic mail addresses;
- (G) Social security numbers;
- (H) Medical record numbers;
- (I) Health plan beneficiary numbers;
- (J) Account numbers;
- (K) Certificate/license numbers;
- (L) Vehicle identifiers and serial numbers, including license plate numbers;
- (M) Device identifiers and serial numbers;
- (N) Web Universal Resource Locators (URLs);
- (O) Internet Protocol (IP) address numbers;
- (P) Biometric identifiers, including finger and voice prints;
- (Q) Full face photographic images and any comparable images; and
- (R) Any other unique identifying number, characteristic, or code.

## Limited Data Set

The Privacy Rule allows the use of a "limited data set" for research purposes. A limited data set is one in which direct identifiers have been removed, but certain potential identifiers remain. Use of a limited data set is contingent upon the negotiation of a data use agreement.

A limited data set is protected health information that excludes the following direct identifiers of the individual *and of relatives, employers, or household members of the individual*:

- A) Names;
- B) Street address/Postal address information, other than town or city, State, and zip code;\*
- C) Telephone and fax numbers;
- D) Electronic mail addresses;
- E) Social security numbers;
- F) Medical record numbers, health plan beneficiary numbers or other account numbers;
- G) Certificate/license numbers;
- H) Vehicle identifiers and serial numbers, including license plate numbers
- I) Device identifiers and serial numbers;
- J) Web universal resource locators (URLs) or Internet protocol (IP) address numbers;
- K) Biometric identifiers, including finger and voice prints; and
- L) Full face photographic images and any comparable images.

\*Unlike de-identified data, the limited data set may include five-digit zip code or any other geographic subdivisions, such as State, county, city, precinct and their equivalent geocodes. These geographic designations are permitted in order to support a range of research and public health activities, such as the analysis of local variations in disease burdens or statistics on the provision of health care services.

A limited data set is considered to be protected health information under the Privacy Rule. Prior to using the limited data set, the researcher must submit a data use agreement to the holder of the medical record. The agreement must contain the following elements:

- The permitted uses and disclosures by the recipient
- The approved users and recipients of the data
- Agreement by the recipient not to re-identify the data or contact the individuals
- Assurances that the recipient will use appropriate safeguards to prevent use or disclosure of the limited data set other than as permitted by the data use agreement
- Agreement that the researcher will report to the covered entity any uses or disclosures of the limited data set which were not specifically allowed
- Agreement to require that any agents and subcontractors adhere to the same safeguards

Accounting requirements: Disclosures in a limited data set are excluded from the “accounting for disclosures” requirement since direct identifiers are removed. .

### **Reviews that are Preparatory to Research**

The researcher may access protected health information if he/she attests that:

- The information is being sought solely to prepare a research protocol or for similar purposes preparatory to research.
- No protected health information is to be removed from the covered entity by the researcher.
- The information being sought is necessary for research purposes.

This provision may be useful for examining medical records in order to formulate hypotheses, assess feasibility of a project, or determine availability of data. Researchers may **review**

identifiable data in order to make these determinations; however, HIPAA requires that any information recorded in that review must meet de-identification standards.

Accounting requirements: HIPAA regulations require that when a medical record is accessed for activities preparatory to research, the researcher's access must be included in the patient's accounting of disclosures. For disclosures of less than 50 records, the disclosure must be tracked for each individual. For disclosures of 50+ records, covered entities are allowed to use a simplified accounting procedure by tracking the study title, description and type of protected health information sought, and the timeframe of the disclosure. When an individual requests an accounting, the covered entity must assist him/her in contacting those researchers to whom it is likely that the individual's information was actually disclosed.

### **Waiver of Individual Authorization**

An IRB or privacy board may waive the requirement for individual, written authorization under certain conditions. Individual authorization may be waived if the research meets the following criteria:

- (A) The use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals based on, at least, the presence of the following elements;
  - i. An adequate plan to protect the identifiers from improper use and disclosure;
  - ii. An adequate plan to destroy the identifier 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; and
  - iii. 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 by the Privacy Rule;
- (B) The research could not practicably be conducted without the alteration or waiver;  
and
- (C) The research could not practicably be conducted without access to and use of the protected health information.

Accounting requirements: HIPAA regulations require that when individual authorization is waived, the researcher's access must be included in the patient's accounting of disclosures. For disclosures of less than 50 records, the disclosure must be tracked for each individual. For disclosures of 50+ records, covered entities are allowed to use a simplified accounting procedure by tracking the study title, description and type of protected health information sought, and the timeframe of the disclosure. When an individual requests an accounting, the covered entity must assist him/her in contacting those researchers to whom it is likely that the individual's information was actually disclosed

## Research on Decedents

Research on decedents is not subject to human subject regulations; however, it is subject to the HIPAA Privacy Rule. In order to access medical records on decedents, the researcher must provide the holder of the medical record with assurances that:

- The information being sought is solely for research on decedents
- The information being sought is necessary for research purposes

The covered entity has a right to require documentation of the death of the individuals.

Accounting requirements: HIPAA regulations require that when a medical record is accessed for research on decedents, the researcher's access must be included in the patient's accounting of disclosures. For disclosures of less than 50 records, the disclosure must be tracked for each individual. For disclosures of 50+ records, covered entities are allowed to use a simplified accounting procedure by tracking the study title, description and type of protected health information sought, and the timeframe of the disclosure. When an individual requests an accounting, the covered entity must assist him/her in contacting those researchers to whom it is likely that the individual's information was actually disclosed

## Transition Requirements for Ongoing Research

Under HIPAA's transition provisions, researchers are allowed to use study-specific protected health information that is collected either before or after April 14, 2003, provided that the subject's written informed consent or an IRB waiver of consent occurred prior to that date. For ongoing studies employing written consent, **new subjects** enrolled after April 14, 2003 must sign a HIPAA privacy authorization in addition to the informed consent document prior to study participation.

Additionally, if currently enrolled subjects are **re-consented** for any reason after April 14, 2003, then HIPAA privacy authorization must be obtained with the revised consent.

Ongoing studies that are being conducted under an IRB-approved waiver of informed consent may continue without interruption under the Privacy Rule's transition provisions, provided that informed consent is not sought from the subject at a later date. If informed consent is sought, consent must be accompanied by a HIPAA authorization.

**NOTE: Previously-approved exempt studies are not grandfathered in. If a researcher plans to collect data on an exempt project after April 14, 2003, the project must undergo a HIPAA privacy review prior to that data collection.**

For questions, please contact the HIPAA Compliance Office at (913) 588-0940.