HIPAA Guidance for Researchers

Definitions

HIPAA authorization - consent obtained from a patient or health plan member that permits a covered entity or business associate to use or disclose PHI to an individual/entity for a purpose that would otherwise not be permitted by the HIPAA Privacy Rule.

Protected Health Information (PHI) - Protected health information includes all individually identifiable health information, including demographic data, medical histories, test results, insurance information, and other information used to identify a patient or provide healthcare services or healthcare coverage. 'Protected' means the information is protected under the HIPAA Privacy Rule.

Elements of an authorization form

In addition to securing informed consent, researchers are required to obtain a separate authorization from subjects for the release of PHI. Authorization can be accomplished either by having the subject consent to release of their protected health information and sign a completed Authorization to Release Health Information from Woman's Hospital form or a separate authorization that contains the following elements:

· A description of the PHI to be used or disclosed that identifies the information in a specific and meaningful fashion;

· Person or class of persons who make the requested use or disclosure;

· Person or class of persons to whom the hospital may make the requested use or disclosure;

· Purposes of the use or disclosure;

· The possibility of re-disclosure;

· Expiration date, which may be the end of the research study or none (unless for the release of genetic test results, which may be for no more than 60 days);

· Right to revoke the authorization and description of how the individual may revoke the authorization;

· The ability or inability to condition treatment, payment, etc. on the authorization; **AND**

· Signature of the individual and date.

If the authorization is signed by a personal representative of the individual, a description of such representative's authority to act for the individual must be provided. The IRB must approve all authorization forms. Once the authorization form has been approved by the IRB, the investigator must use that version of the form. An IRB approval stamp will be affixed to the approved

version. The IRB must approve any proposed changes to the authorization form prior to implementation.

Genetic information

Louisiana law permits releases of genetic information "anonymous research where the identity of the individual will not be released." [Louisiana Revised Statutes Annotated Section 22:213.7 D.]

■ Louisiana laws which state that an insured's or enrollee's genetic information is the property of the insured or enrollee do not apply to genetic information obtained for anonymous research where the identity of the subject will not be released. [Louisiana Revised Statutes Annotated Section 22:213.7 D.]
■ A general authorization for the release of medical records does not serve as an authorization for the disclosure of genetic information. [Louisiana Revised Statutes Annotated Section 22:213.7 C(5).]

Authorization for disclosure of genetic information must be written, and adhere to the format specified by statute, including describing the specific genetic information to be disclosed and stating the date upon which the authorization will expire, which may not be more than sixty days from the date of authorization. [Louisiana Revised Statutes Annotated Section 22:213.7 C(2).]

Louisiana) permit the use of "genetic information" for research purposes when the identity of the individual is not disclosed. Thus, while these provisions appear restrictive, they permit the use and retention of genetic information for research purposes when the data are anonymous.

According to Louisiana law, special consent is required to release genetic test results to a third party. An individual is the owner of his/her genetic information. This special consent should be present in the informed consent form and in a special consent section of the authorization to release protected health information (HIPAA) form.

According to Louisiana law, special consent for the release of genetic test results is only valid if it includes the following:

a. Identify the person permitted to make the disclosure;
b. Describe the specific genetic information to be disclosed;
c. Identify the person to whom the information is to be disclosed;
d. Describe with specificity the purpose for the disclosure;
e. State the date upon which the authorization will expire, which in no event shall be more than 60 days after the date of the authorization;
f. Include a statement that the authorization is subject to revocation at any time before the disclosure is actually made; **AND**
g. Include a statement that the authorization shall be invalid if used for any purpose other than the designated purpose.

Waiver of authorization

In some circumstances, authorizations for the use or disclosure of PHI may be waived by the IRB Chair or IRB, provided:

1. The principal investigator has requested a waiver of authorization;

2. All of the following criteria are satisfied and documented:

a). The use or disclosure of PHI involves no more than a minimal risk to the privacy of individuals, based on the presence of at least the following elements:
1). An adequate plan to protect the identifiers from improper use and disclosure;

2). 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**

3). 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 protected information would be permitted;

b). The research could not practicably be conducted without the waiver or alteration; **AND**

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

3. The IRB shall maintain the following documentation of approval of an alteration or waiver of authorization as follows:

a. A statement identifying the IRB and the date on which the alteration or waiver of authorization was approved.

b. A statement the IRB determined that the alteration or waiver satisfies the criteria for waiver listed above.

c. A brief description of the PHI for which use or access has been determined to be necessary by the IRB

d. A statement that the alteration or waiver of authorization has been reviewed and approved under either normal or expedited review procedures; **AND**

e. The documentation is signed by the IRB Chair.

NOTE: Uses or disclosures of PHI made pursuant to a waiver are subject to the minimum necessary rule. When using or disclosing PHI, a covered entity must make reasonable efforts to limit PHI to the minimum necessary to accomplish the intended purpose of the use or disclosure.

4). If a waiver of authorization is approved, a form detailing the accounting of the disclosures of PHI should be submitted to Health Information Management. The form may be requested from the Woman's Hospital Research Center or found on the Woman's Hospital Intranet under IRB Policies and Procedures.

Tracking of disclosures

HIPAA rules require that a record be made of a disclosure of any personally identifiable information that is made without an authorization by the research participant. Therefore, tracking of disclosures will have to be undertaken for all disclosures if a waiver of authorization, an approval for review preparatory to research, or an approval for the use of a decedent's PHI is obtained for purposes of research, and for any disclosures not previously specified in a signed authorization document.

The following information about any disclosure must be recorded and made available upon request to the individual who is the subject of the PHI:

1. Date of disclosure;

2. Name of person/entity that received the PHI;

3. Description of what PHI was disclosed; and

4. Brief statement regarding the purpose of the disclosure.

Disclosures for >50 participants

HIPAA rules allow a modified tracking method for research that involves the disclosure of PHI from more than 50 people and for which authorization has been waived. In this instance it is unnecessary to maintain a list of the specific persons about whom PHI has been disclosed, but the following information must be available upon the request of any individual whose information may have been included:

1. The name and description of all protocols involving 50 or more people for which authorization has been waived, including the purpose of these and criteria for selecting records, if the individual's information may have been included;

2. Brief descriptions of types of PHI disclosed;

3. Dates or time periods during which disclosures occurred;

4. Contact information (name, address, telephone number) for sponsors and recipient researchers;

5. Statement that a specific individual's PHI may or may not have been disclosed for a particular protocol or research activity.

In addition, the researcher must also assist in contacting the sponsor and recipient researcher if it is reasonably likely that an individual's PHI was disclosed to them. The principal investigator must submit all tracking of disclosure information to the IRB to be sent to Health Information Management.