Issuing Department: Human Subjects Protection Program
Policy Number: 2011-014.0
Policy Title: Health Insurance Portability and Accountability Act (HIPAA) in Research

Purpose

The purpose of this policy is to set forth the requirements for compliance with the HIPAA regulation as related to human subject research.

Definitions

See policy 2011-007.0 for definitions of:

Disclosure | Protected Health Information | Use

Policy

Unless grandfathered by the transition provisions, as of April 14, 2003 all studies that include protected health information (PHI) of subjects must be compliant with the HIPAA regulation. The IRB panels and respective Chairs will act as the Privacy Board for UCHC research studies. The investigator may demonstrate compliance with HIPAA by one of the following methods.

Authorization to Use and Disclose Protected Health Information: It is expected that the majority of studies enrolling subjects will seek an Authorization to Use and Disclose Protected Health Information from the subject. Such authorization must be obtained prior to the use and / or disclosure of protected health information.

Unless exceptions are granted by the IRB (e.g. UConn Health involvement in a study is limited to data analysis and collaborating site is obtaining authorization) the authorization is a document apart from the informed consent document. Investigators are required to use the approved template available from the HSPP/IRB web site. The completed forms must be submitted to the IRB for review and approval as part of the initial application and at the time of continuing review.

A valid authorization must contain all of the following elements:

- a specific and meaningful description of the information to be used and / or disclosed;
- the name or other specific identification of the person(s), or class of persons, authorized to make the requested use or disclosure;
- the name or other specific identification of the person (s), or class of persons, to whom the covered entity may make the requested user 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 (statements such as “end of the research study,” “none,” or similar language is sufficient for a research authorization) (Note: if an expiration date is not included the authorization must be retained permanently.);
- signature of the individual and date (if signed by a representative, a description of such representative’s authority to act for the individual must also be provided).

Statements addressing the following elements must also be included:

- that the individual has the right to revoke the authorization in writing (provide name and address of whom to send the notice of revocation) except that the researcher may continue to use and disclose information that had already been collected and acted upon pursuant to the authorization and prior to the revocation;
- that non-research clinical treatment will not be conditioned upon signing a research authorization;
- that enrollment in the research study will be conditioned upon signing the authorization; and
- that information disclosed under the authorization could potentially be re-disclosed by the recipient and may no longer be protected under HIPAA.

The authorization must be written in plain language. Individuals must be provided with information on the privacy practices of UConn Health when signing an authorization to enroll in a study conducted at UConn Health.

Use of De-Identified Data: If information is de-identified it is not considered protected health information and the HIPAA regulation does not apply. The investigator is required to sign and submit to the IRB a form certifying the use of de-identified data. The form is available from the HSPO/IRB web site. In order to meet the criteria of being de-identified the 18 identifiers defined within the HIPAA regulations and noted below cannot be included in a data set.

Information that is considered to be an identifier includes the following:

- name
- phone number
- fax number
- social security number
- account number
- certification/license Number
- device identifiers and serial numbers
- i.p. addresses
- photographic images
- geographic subdivisions smaller than a state
- all elements of date, except year (except that ages over 89 must be reported in aggregate)
- e-mail address
- medical record numbers
- health plan beneficiary numbers
- vehicle identifiers and serial numbers
- web u.r.l.s
- biometric identifiers
- any other unique identifying number, characteristic or code

A code may be assigned by someone other than the investigator to de-identified data that allows it to be re-identified if necessary. The code cannot be derived from any identifiable piece of information or combination of pieces of identifiable information. The key to the code cannot be accessible to the investigator or research personnel using the de-identified data.

There are three mechanisms by which an investigator may certify de-identification:

Creation of De-identified Data: A member of the UCHC may use identifiable information to create a de-identified data set. The principal investigator and, if different, individual(s) creating the de-identified data set must certify that no identifiable protected health information is recorded, that no link can be made back to the individual, and that any information seen in the course of creating the data set will be kept confidential.

Use and / or Disclosure of De-identified Data: The investigator may certify that no identifiers are used, reviewed or recorded during the course of the study.

Statistical De-identification: An individual with appropriate statistical and scientific knowledge may certify that the information is not identifiable. The analysis must be done on each identifier that is included in the data set. It must be determined that the risk is very small that the information could be used, alone or in combination with other available information, by the intended recipient to identify an individual who is the subject of the information. In conjunction with the Certification of De-Identification submitted to the IRB the principal investigator must provide documentation from the statistician that includes the date of the analysis, the methods(s) used, the results obtained, a statement that the likelihood of re-identification is very small, and the name, credentials, signature of the statistician and the date of signature.

3. Limited Date Set/Data Use Agreement: If an authorization or waiver are not applicable, if indirect identifiers must be kept within a limited data set (LDS) in order to perform the research study and the information is to be disclosed outside of UConn Health, the principal investigator must enter into a Data Use Agreement (DUA) with the data recipient. A DUA may also be utilized when UConn Health is the recipient of a LDS. Only after the agreement has been executed can the limited data set be used/disclosed.

At UConn Health, for research related activities, LDS/DUAs are executed by either the Office of Clinical and Translation Research (OCTR) or the Office of Sponsored Programs (ORSP). The investigator must submit the details of the information to be contained within the limited data set to OCTR/ORSP for review and approval in conjunction with the Data Use Agreement. The elements of the LDA may be defined within the DUA. When the activity constitutes human subject research the executed LDS/DUA is to be submitted as part of the IRB submission. They IRB may grant contingent approval while the LDS/DUA is in the process of being executed.

The data contained within the limited data set must be the minimum necessary to conduct the research project.

The indirect identifiers that may be included in a limited data set include town, city, state and zip code, and dates directly related to an individual, including birth date, admission date, discharge date and date of death. The limited data set may not include any other identifier listed under method 2 that is related to the individual, the individual's relatives, employers, or household members.

4. Use of Information as Preparatory to Research: Investigators seeking to review charts or other sources of information that contain PHI to determine the feasibility of a study must first get approval from the IRB. The investigator must submit a form to the IRB to request permission for the review, to confirm that the review is necessary to prepare a research protocol, to certify that no protected health information will be removed from the institution, and to certify that the information to be reviewed is necessary for the research purpose. The review may begin only after the IRB Chair, acting as a member of the HIPAA privacy board, approves the request.

The preparatory to research allowance will only be approved for determining the feasibility of conducting a study. It may not be used to contact subjects for recruitment purposes.

Only the minimum PHI necessary to determine the feasibility of the study may be used.

The owner of the data that the investigator is seeking to review may require the investigator to provide proof that the IRB has approved the request as preparatory to research.

5. Use of Information on Decedents: Investigators seeking to review chart information on deceased individuals must submit a form to the IRB to request permission to conduct the review. The investigator must certify that the PHI is necessary to conduct a research project and is being sought solely for research on the decedents (not living relatives of the decedent), and to certify that the information to be reviewed is necessary for the research purpose. The initial review may begin only after the IRB Chair, acting as a member of the HIPAA privacy board, authorizes the request. Such studies are not considered human subject research and are not subject to continuing review or audit. The review is conducted to ensure that adequate procedures are in place to ensure confidentiality.

The IRB may require proof of death of the study subjects.

Only the minimum PHI necessary to conduct the study may be used.

The owner of the data that the investigator is seeking to review may require the investigator to provide proof that the IRB has approved the request to perform research on decedent information.

The IRB which also acts as the privacy board must review such activities to ensure that the privacy rights of the deceased and / or the family of the deceased are protected. Such activities are not subject to continuing review or audit. The Chair may authorize such requests.

6. Waiver/Alteration of Authorization to Use and Disclose PHI: Under certain circumstances it is possible to conduct research using protected health information without an authorization. The principal investigator must submit a request for waiver of authorization to the IRB for review and approval. To approve the waiver the following elements must be satisfied:

- the use and / or disclosure of PHI involves no more than a minimal risk to the privacy of individuals;
- the research could not practicably be conducted without the waiver; and
- the research could not practicably be conducted without access to and the use of the PHI.

To ensure that risks to privacy are minimized the principal investigator must address:

- plans to protect identifiers from improper use and disclosure;
- plans to destroy the identifiers at the earliest opportunity consistent with the conduct of the research (unless justification for retaining the identifiers or such retention is otherwise required by law); and
- assurance that the PHI will not be reused or disclosed, except as required by law for authorized oversight of the project.

The IRB shall maintain the following documentation about the waiver:

- identification of the responsible IRB panel or Chair or reviewing member
- the signature of the Chair or reviewing member
- the date on which the waiver was approved
- that the criteria to approve the waiver have been satisfied
- the type of review conducted on the waiver (full board vs. expedited)

Waivers may be granted for a portion of a study. This is referred to as a partial waiver.

The required elements of an authorization may also be altered using the waiver process identified above.

Only the minimum necessary PHI to conduct the study may be sought by the investigator. An accounting of any disclosures must be maintained for any PHI disclosed under a valid waiver or partial waiver.

Procedure:

The principal investigator completes and submits the relevant HIPAA template form(s) as part of an IRB application.

The reviewer reviews and approves the document as part of the submission, requiring changes to secure approval if necessary.

Related Content

2009-011.3 – Institutional Review Board – Expedited Reviews
2009-011.5 – Institutional Review Board – Review by Convened Board

Basis

45 CFR 164

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Reviewed and Approved By:

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