HIPAA Application in UNA Human Subject Research

Background

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) and its regulations, including the Privacy Rule and the Security Rule, govern the way certain health information is collected, maintained, used, and disclosed by covered entities. Covered entities include:

- Health insurers
- Health care clearinghouses
- Health care providers who electronically transmit information for certain types of transactions such as billing and eligibility verification.

The Privacy Rule establishes a set of safeguards on certain types of health information known as protected health information, or PHI, and provides a national minimum level of protection for that information. PHI is health information that is individually identifiable and created or held by a covered entity. It includes past, present, and future health information (mental and physical) about the:

- Health history or condition of an individual,
- Provision of care to an individual, or
- Payment for an individual's care.

The HIPAA Privacy Rule also establishes the conditions under which protected health information may be used or disclosed by covered entities for research purposes. Research is defined in the Privacy Rule as, "a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge." See 45 CFR 164.501. The Privacy Rule affects research and researchers when either:

- Research creates or generates PHI, or
- Research requires access to and/or use of PHI.

A covered entity may always use or disclose for research purposes health information which has been de-identified (per 45 CFR 164.502(d), and 164.514(a)-(c) of the Rule) without regard to the provisions below.

The Privacy Rule also defines the means by which individuals will be informed of uses and disclosures of their medical information for research purposes, and their rights to access information about them held by covered entities. Where research is concerned, the Privacy Rule protects the privacy of individually identifiable health information, while at the same time ensuring that researchers continue to have access to medical information necessary to conduct vital research. Currently, most research involving human subjects operates under the Common Rule (45 CFR Part 46, Subpart A) and/or the Food and Drug Administration's (FDA) human subject protection regulations (21 CFR Parts 50 and 56), which have some provisions that are similar to, but separate from, the Privacy Rule's provisions for research. These human subject protection regulations, which apply to most Federally-funded and to some privately funded research, include protections to help ensure the privacy of subjects and the confidentiality of information. The Privacy Rule builds upon these existing Federal protections. More importantly, the Privacy Rule creates equal standards of privacy protection for research governed by the existing Federal human subject regulations and research that is not.

How the Rule Works

In the course of conducting research, researchers may obtain, create, use, and/or disclose individually identifiable health information. Under the Privacy Rule, covered entities are permitted to use and disclose protected health information for research with individual authorization, or without individual authorization under limited circumstances set forth in the Privacy Rule.

De-Identified Data

De-identified data are not subject to the requirements of the Privacy Rule because they are not individually identifiable. There are two ways to de-identify data:

Safe Harbor Method – in which all of the following elements are removed from a data set:

1. Name
2. All geographic subdivisions smaller than a state (street address, city, county, precinct) Note: zip code or equivalents must be removed, but can retain first 3 digits of the geographic unit to which the zip code applies if the zip code area contains more than 20,000 people
3. For dates directly related to the individual, all elements of dates, except year (date of birth, admission date, discharge date, date of death)
4. All ages over 89 or dates indicating such an age
5. Telephone number
6. Fax number
7. Email address
8. Social security number
9. Medical record number
10. Health plan number
11. Account numbers
12. Certificate or license numbers
13. Vehicle identification/serial numbers, including license plate numbers
14. Device identification/serial numbers
15. Universal Resource Locators (URLs)
16. Internet protocol (IP) addresses
17. Biometric identifiers, including finger and voice prints
18. Full face photographs and comparable images
19. Any other unique identifying number, characteristic, or code.

Note: Item 19 is known as the “catch-all” provision and is intended to include items that are not otherwise specified but could make a data set identifiable.

Statistical Method – in which certification is provided by "a person with appropriate knowledge of and experience with generally accepted statistical and scientific principles and methods for rendering information not individually identifiable so that there is a ‘very small’ risk that the information could be used by the recipient to identify the individual who is the subject of the information, alone or in combination with other reasonably available information.

How Can Researchers Use PHI and Comply With HIPAA Requirements?

Researchers accessing or using PHI can obtain:

- Authorization
- Waiver or partial waiver of authorization
- Alteration of authorization

Note: The regulation identifies a Privacy Board as having responsibility for reviewing requests for waiver or alteration of the authorization requirement. Under the Privacy Rule an IRB may serve as a Privacy Board. At UNA the HSC will serve as the Privacy Board.

Authorization

Although similar to informed consent, Authorization focuses on privacy risks and the use or disclosure of PHI. An Authorization must state how, why, and to whom the PHI will be used and/or disclosed for research purposes. An Authorization may not require an expiration date; consult state and/or local law. However, a research participant has the right to revoke (in writing) his/her Authorization at any time. The participant or the participant's authorized representative must be given a signed copy of the Authorization and researchers must keep a signed copy of participants' Authorization for six years.

HIPAA Authorization Form for Use of PHI
HIPAA Authorization Form Instructions for Use of PHI

Waiver or Partial Waiver of Authorization

The requirement to obtain Authorization may be waived if all of the following criteria are met:

- Use or disclosure of PHI involves no more than minimal risk to the privacy of individuals, based on:
    - 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 conduct of the research (unless a health or research justification for retaining the identifiers exists or retention is required by law)
    - 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) or for other research for which use/disclosure of PHI would be permitted
- Waiver will not adversely affect the privacy rights and the welfare of the individuals
- The research could not practicably be conducted without the waiver
- The research could not practicably be conducted without access to and use of the PHI.

Authorization may be waived for all, or only some uses of PHI for a particular study. At UNA a "partial waiver" permits the use of PHI for recruitment purposes only, to allow identification and, as appropriate, contact of potential participants to determine their interest in study participation. A subject who agrees to participate in the research must then sign a research authorization form unless an alteration of authorization has also been approved by the HSC. To request a waiver complete the waiver request form:

HIPAA Waiver or Alteration of Research Authorization Form

Alteration of Authorization

The requirement to obtain Authorization for use of PHI may also be "altered" for a specific study. An alteration allows a change in certain Authorization requirements, while still requiring authorization for the use of PHI. Examples include making an exception to the required language in an authorization or to the requirement to obtain a signed Authorization. To be granted, an alteration must meet the same criteria as a waiver or partial waiver. To request an alteration of Authorization, use the Waiver for Alteration of Research Authorization form linked above.

Limited-Data Sets

A limited data set is a special category of PHI that has all of the following identifiers removed:

1. Name
2. Postal address information other than town/city, state, and zip
3. Telephone number
4. Fax number
5. Email address
6. Social security number
7. Medical record number
8. Health plan number
9. Account numbers
10. Certificate or license numbers
11. Vehicle identification/serial numbers, including license plate numbers
12. Device identification/serial numbers
13. Universal resource locators (URLs)
14. Internet protocol (IP) addresses
15. Biometric identifiers, including finger and voice prints
16. Full face photographs and comparable images

Under the Privacy Rule, use or disclosure of limited data sets for research purposes requires a "Data Use Agreement."

HIPAA Data Use Agreement Form

Reviews Preparatory to Research

The Privacy Rule also permits certain activities involving use or disclosure of PHI without Authorization. The "preparatory to research" provision permits researchers to use PHI for limited purposes, such as a feasibility assessment (e.g., whether a sufficient population exists to conduct research). However, the Privacy Rule does not permit the researcher to remove PHI. To comply with both the Privacy Rule and human subjects protection regulations, UBA researchers are permitted to review PHI, but identifiers may not be recorded; and researchers may not use the preparatory-to-research provision to identify or recruit specific individuals for a study.

To conduct a review preparatory to research, a researcher must provide all of the following representations:

- The use or disclosure is requested solely to review PHI as necessary to develop a research protocol or for similar purposes preparatory to research
- PHI will not be removed in the course of review

- The PHI for which use or access is requested is necessary for the research.

Research Involving PHI About Decedents

The Privacy Rule provides protections to living and deceased individuals.

To use decedents' PHI for research purposes, a researcher must provide all of the following:

- Representation that the use or disclosure is solely for research involving the PHI of decedents (e.g., and not also the living relatives of decedents)
- Representation that the PHI is necessary for the research
- Documentation (at the request of the covered entity holding the PHI) of the death of the individuals whose PHI is sought.

Note: If the participant population contains both living and deceased individuals, the requirements for Authorization (or waiver or alteration) apply.