

Policy Number: 49

Title: Health Insurance Portability and Accountability Act (HIPAA)

Date of Last Revision: July 5, 2007

I. Introduction

The HIPAA Privacy Rule, effective April 14, 2003, established national standards to safeguard the privacy of a patient's protected health information. Protected health information (PHI) includes: Information created or received by a health care provider or health plan that includes health information or health care payment information plus information that personally identifies the individual patient or plan member. Personal identifiers include: a patient's name and email, web site and home addresses; identifying numbers (including Social Security, medical records, insurance numbers, biomedical devices, vehicle identifiers and license numbers); full facial photos and other biometric identifiers; and dates (such as birth date, dates of admission and discharge, death).

In May 2002, the University of California (UC) Board of Regents designated the University of California as a HIPAA hybrid covered entity and determined that UC would be a Single Health Care Component for the purposes of complying with the HIPAA Rule. All UC entities covered by the HIPAA Privacy and Security Rules — medical centers, medical clinics, health care providers, health plans, student health centers — are a single entity for purposes of compliance with HIPAA.

The UCLA IRB, in its role as the Privacy Board for University of California, Los Angeles (UCLA) HIPAA covered human subjects research, will ensure that research PHI is used, stored and/or disclosed according to current HIPAA regulations. All UCLA research related disclosures of PHI must obtain prospective approval by a UCLA Institutional Review Board (IRB). In general, except for treatment, payment, and operations (TPO) investigators are limited to the minimum PHI reasonably necessary to conduct the research.

II. Definitions

Authorization: Under HIPAA, the granting of rights to access PHI. Required by HIPAA for disclosures or uses other than for 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 health plan, a health care clearinghouse, or a health care provider who transmits 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 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: (1) 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 (2) 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.

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

1. the past, present, or future physical or mental health or condition of an individual,
2. the provision of health care to an individual, or
3. 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.

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 the 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 Health Information (RHI) is defined as data used in research that would be personally identifiable but not considered PHI and is therefore not subject to the HIPAA Privacy and Security Rules. The key distinction between RHI and PHI is that PHI is associated with or derived from a healthcare service event, i.e., the provision of care or payment for care. RHI is not associated or derived from the provision of care or payment for care. RHI is covered by other state and federal laws for privacy and confidentiality of research health information.

Single Health Care Component: HIPAA permits a complex organization to define itself as a single entity under HIPAA, thus providing a single set of policies, procedures and standards, permitting use of uniform forms and allowing movement of PHI within this single entity under the notice of privacy practices.

III. Eighteen HIPAA Identifiers

Following are the *18 identifiers* recognized under HIPAA:

1. Names;
2. All geographical 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. Phone 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; and
18. Any other unique identifying number, characteristic, or code (note this does not mean the unique code assigned by the investigator to code the data)

IV. IRB Responsibility

- A. The IRB will review all instances where investigators create, use, or exchange individually identifiable health information when conducting human subjects research.

- B. The IRB will review all IRB applications and human subject research proposals for adequate privacy measures to maintain the confidentiality of the research participants and their data in order to assure compliance with HIPAA as it relates to research.
- C. The IRB will determine whether subjects' authorization to use or disclose PHI must be obtained or may be waived.

V. Investigator Responsibility

- A. The Investigator is responsible for identifying in his/her application to the IRB all proposed access to PHI which will occur during the course of the research, including access to paper and electronic medical records for the purpose of subject identification or screening, any intended addition of information into medical records, and any collection or use of human specimens with individually identifiable health information attached.
- B. For studies intending to obtain subjects' authorization to use or disclose PHI, the Investigator must complete Sections I and II(A) of the UCLA HS-1(a) HIPAA Research Application in order to obtain UCLA IRB approval for the use/disclosure.
 - 1. The Investigator is responsible for using the standard *University of California Permission to Use Personal Health Information for Research* for access to any UC-held medical record. For access to a subject's non-UC medical records, the HIPAA research authorization form of the subject's healthcare provider should be used (if the provider does not accept the UC form).
 - a. The form is written and formatted very carefully to comply with both Federal regulations and state law. Except where space is provided for "fill in the blank" information, neither the format nor the content of the UC form may be modified, nor may the form be integrated into the consent form.
 - b. To avoid the potential to provide conflicting information to subjects, HIPAA-related information should not be added to consent forms.
 - c. As the UC form is standard and not modifiable, the Investigator should not submit the form to the IRB for review and approval. The IRB will not issue a stamped version of the form.
- C. For studies requesting a waiver of authorization to use or disclose PHI, the Investigator must complete Sections I, II(B), and II(B)(1) of the UCLA HS-1(a) HIPAA Research Application in order to obtain UCLA IRB approval for the use/disclosure without subjects' authorization.
- D. For studies requesting approval to use or disclose a Limited Data Set, the Investigator must complete Sections I, II(B), and II(B)(2) of the UCLA HS-1(a) HIPAA Research

Application in order to obtain UCLA IRB approval for the use/disclosure without subjects' authorization.

- E. For studies requesting approval to use or disclose data which has been Deidentified to meet the Safe Harbor Standard, the Investigator must complete Sections I, II(B), and II(B)(3) of the UCLA HS-1(a) HIPAA Research Application in order to obtain UCLA IRB approval for the use/disclosure without subjects' authorization.
- F. For studies requesting approval to use or disclose data which has been Deidentified to meet the Statistical Standard, the Investigator must complete Sections I, II(B), and II(B)(4) of the UCLA HS-1(a) HIPAA Research Application in order to obtain UCLA IRB approval for the use/disclosure without subjects' authorization.
- G. The Investigator is responsible for identifying and complying with HIPAA policies and procedures, as well as applicable State or Federal regulations governing access to PHI outside the University of California hybrid covered entity.

VI. University of California Requirements for Use and Disclosure of PHI For Purposes “Preparatory to Research”

Although HIPAA includes provisions for investigators to use or disclose PHI without IRB review for the development of a research protocol and/or to assess a research question or hypothesis, University of California policy does not allow such use. The University of California considers the accessing of PHI for purposes preparatory to research to constitute a human subject research activity subject to review and approval by an authorized IRB.¹

Investigators who intend to access medical records to prepare a research protocol must complete and submit the UCLA Form HS-9, “Application for Research Review of Medical Records” to obtain UCLA IRB review and approval prior to access to the medical records. Any access to medical records, querying of databases for any type of individually identifiable health information, or any activity where PHI is accessed to prepare a research protocol requires submission of the HS-9 Form for UCLA IRB review and approval.

Regulations:

45 CFR 160

45 CFR 164

California Civil Code Sections 56-56.16 (California Confidentiality of Medical Information Act)

¹ Please refer to University of California guidance on HIPAA and Research at UC at http://www.universityofcalifornia.edu/hipaa/docs/research_guidelines.pdf

References:

U.S. Department of Health and Human Services, Office for Civil Rights HIPAA Webpage
<http://www.hhs.gov/ocr/hipaa/>

California Office of HIPAA Implementation Webpage. <http://www.ohi.ca.gov>

UCLA OPRS HIPAA page. <http://www.oprs.ucla.edu/human/forms/HIPAA>

UC HIPAA Research page. <http://www.universityofcalifornia.edu/hipaa/research.html>

Attachments:

- UCLA-13 UCLA Research: Complying with HIPAA
<http://www.oprs.ucla.edu/human/documents/pdf/HRGuidance.pdf>
- UC-14 University of California ("UC") HIPAA Guidance on HIPAA and Research at UC
http://www.universityofcalifornia.edu/hipaa/docs/research_guidelines.pdf
- UC-15 University of California: Research and Privacy Protection at the University of California Frequently Asked Questions About the UC Research Authorization Form
http://www.universityofcalifornia.edu/hipaa/docs/research_faqs.pdf
- UC-16 University of California Systemwide HIPAA Implementation Taskforce position paper, "What is and is not Protected Health Information in Research Settings: Research-related Health Information (RHI) and Its Relation to HIPAA PHI."
<http://cphs.berkeley.edu/content/hipaa/WhatIsandIsNotPHI.pdf>