

HIPAA AND HUMAN SUBJECTS RESEARCH

This document provides guidance for researchers wishing to use, disclose or create Protected Health Information (PHI). Should you need additional assistance, please contact OPHS at 510-642-7461 or ophs@berkeley.edu.

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A. Introduction

The Health Insurance Portability and Accountability Act (HIPAA) of 1996 was enacted by the U.S. Congress to regulate the protection of private health information for individuals. HIPAA's **Privacy Rule** establishes the conditions under which a *covered entity* can provide researchers access to and use of *protected health information (PHI)* when necessary to conduct research. The Privacy Rule applies only to PHI held or maintained by a covered entity, its business associate, and anyone "downstream" of a business associate (e.g., a sub-contractee who maintains PHI) acting for the covered entity.

When Do Researchers Need to Apply to CPHS?

If a study conducted by a UC Berkeley researcher will involve use, disclosure or creation of UCB PHI, an application must be submitted to CPHS for review and approval. Researchers planning to use PHI held by an outside institution (non-UCB PHI) are also required to submit an application to CPHS for review, but must follow the HIPAA requirements of the institution(s) holding those records.

B. Important Concepts

1. What Is a Covered Entity?

A *covered entity* is a *health plan*, a *health care clearinghouse*, or a *health care provider* who electronically transmits health information in connection with a transaction for which the US Department of Health and Human Services (HHS) has adopted a standard (e.g., transactions concerning billing and payment for services or insurance coverage). A covered entity can be an institution, organization, or individual.

2. Is UC Berkeley a Covered Entity?

The Regents of the University of California is a covered entity. In 2002, the Board of Regents elected to make the University of California a “*hybrid entity*” under HIPAA, which means the University has both covered and non-covered functions. Most HIPAA regulations only apply to covered functions. Berkeley units within UC’s health care component are *University Health Services (including its health care services on behalf of Intercollegiate Athletics) and the Optometry Clinic*.

Additionally, to the extent that other campus units perform services to these covered components (e.g., storage of PHI, legal, audit, accounting, information technology, Institutional Review Boards, etc.), they are part of the health care component and must comply with the Privacy Rule. Disclosures of PHI by these covered functions to the rest of the University are regulated by the Privacy Rule and treated like disclosures to entities outside the University.

3. When is Research at Berkeley Subject to HIPAA Privacy Requirements?

Research is subject to HIPAA privacy requirements when it is conducted together with the provision of health care services by individuals who are part of a covered component (UHS or Optometry Clinic).

For example, an optometrist who conducts a clinical trial with experimental contact lenses in the course of provisioning routine care to patients would be subject to the HIPAA Privacy Rule and would produce Protected Health Information (PHI) as part of the study.

4. What Is PHI?

Protected Health Information (PHI) is individually identifiable health information (see [list of Personal Identifiers under HIPAA](#)) transmitted or maintained in any form or medium (electronic, oral, or paper) by a covered entity or its business associates. The Privacy Rule protects the PHI of both living and deceased individuals.

See [CPHS/OPHS Glossary](#) for definitions of “Health information” and “Individually identifiable health information.”

Under the Privacy Rule, the definition of PHI excludes individually identifiable health information that is maintained in education records covered by the US Family Educational Rights and Privacy Act (FERPA).

5. De-Identified Health Information:

De-identified health information is a record in which identifying information has been removed to render the health information not subject to HIPAA’s Privacy Rule. Researchers may use or disclose de-identified health information, without restriction, since it is not PHI and thus is not protected by the Privacy Rule.

Covered entities seeking to release health information to researchers must determine that the information has been de-identified using either of the following methods: (1) by removing all 18 elements that could be used to identify the individual or the individual's relatives, employers, or household members (see [list of Personal Identifiers under HIPAA](#)), or (2) by using statistical methods to establish de-identification.

C. How Can PHI Be Accessed for Research?

1. Obtaining Subject Permission through an Authorization Form
2. Obtaining an IRB Waiver or Alteration of Authorization
3. Using a Limited Data Set with a Data Use Agreement
4. Using PHI for Activities Preparatory to Research
5. Use or Disclosure of Decedents' PHI

1. Authorization Form

An **Authorization Form** is a form through which a research subject's signed permission is obtained to allow a covered entity to use and disclose his/her PHI for research purposes. In the case of minors, a signed Authorization Form is obtained from the minor's parent or legal guardian.

Obtaining HIPAA Authorization is required in addition to obtaining informed consent to participate in research. An Authorization Form focuses on privacy risks and states how, why, and to whom the PHI will be used and/or disclosed for research. This Authorization pertains to a specific research study.

The subject must be given a copy of the signed form to keep for his/her records. Also, the researcher must retain the signed form for six (6) years from the date of creation or the date it was last in effect, whichever is later.

Researchers can find a copy of the UC HIPAA Authorization Form available at:

<http://www.ucop.edu/ethics-compliance-audit-services/compliance/hipaa/hipaa-authorization-forms.html>

2. HIPAA Waiver or Alteration of Authorization

A **Waiver or Alteration of Authorization** can be requested when researchers are unable to use de-identified health information and the research could not practicably be conducted if research participants' authorization were required.

For research uses and disclosures of UC Berkeley PHI, the CPHS may approve a waiver or an alteration of the Authorization requirement in whole or in part. A complete waiver is when the CPHS determines that no Authorization is required for use or disclosure of PHI for a particular research project. A partial waiver of Authorization occurs when the CPHS determines that a covered entity does not need Authorization for certain PHI uses and disclosures for research purposes, such as disclosing PHI for research recruitment purposes. An Alteration of Authorization occurs when CPHS is asked to waive one or more required elements of informed consent. For example, if the purpose of the study will not be disclosed to participants in order to avoid bias, this is an alteration because disclosure of the "purpose" is a required element of participant authorization. The CPHS may also approve a request to alter or waive the requirements for Authorization under the condition that some PHI be removed from the proposed use or disclosure.

All of the following criteria must be met for CPHS approval of a waiver or alteration of Authorization requirements for use or disclosure of UC Berkeley patient data:

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

- b. An adequate plan to destroy identifiers at the earliest opportunity consistent with conduct of the research (absent a health or research justification for retaining them or a legal requirement to do so); and
 - c. Adequate written assurances that the PHI will not be reused or disclosed to (shared with) 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 the PHI would be permitted under the Privacy Rule.
2. The research could not practicably be conducted without the waiver or alteration.
 3. The research could not practicably be conducted without access to and use of the PHI.

If a researcher has used or disclosed PHI for research with CPHS approval of a waiver or alteration of Authorization, documentation of that approval must be retained by the researcher for six (6) years from the date of its creation or the date it was last in effect, whichever is later.

3. Limited Data Set with a Data Use Agreement

With the establishment of an appropriate data use agreement (i.e., meets HIPAA requirements, including limiting further use or disclosure of PHI) between the holder of the PHI and the researcher, a limited data set may be used or disclosed for research purposes without obtaining either an individual's Authorization or a waiver or an alteration of Authorization.

A **Limited Data Set** refers to PHI that *excludes* the following 16 categories of direct identifiers under HIPAA:

- | | |
|---|---|
| 1. Names | 10. Certificate/license numbers |
| 2. Postal address information, other than town or city, state, and ZIP Code | 11. Vehicle identifiers and serial numbers, including license plate numbers |
| 3. Telephone numbers | 12. Device identifiers and serial numbers |
| 4. Fax numbers | 13. Web universal resource locators (URLs) |
| 5. Electronic mail addresses | 14. Internet protocol (IP) address numbers |
| 6. Social security numbers | 15. Biometric identifiers, including fingerprints and voiceprints |
| 7. Medical record numbers | 16. Full-face photographic images and any comparable images. |
| 8. Health plan beneficiary numbers | |
| 9. Account numbers | |

The above identifiers must be removed from health information about the individual and the individual's relatives, employers, or household members if the data are to qualify as a limited data set.

4. Activities Preparatory to Research

For activities involved in preparing for research, covered entities may disclose PHI to a researcher without an individual's Authorization, a waiver or an alteration of Authorization, or a data use agreement. However, the covered entity must obtain from the researcher written or oral representations that: (1) the use or disclosure is requested solely to review PHI as necessary to prepare a research protocol or for similar purposes preparatory to research; (2) the PHI will not be removed from the covered entity in the course of review; and (3) the PHI for which use or access is requested is necessary for the research.

5. Decedents' PHI

The Privacy Rule protects the PHI of deceased individuals. Research that uses or discloses decedent PHI must comply with applicable HIPAA regulations. (Note that HIPAA protections cease for PHI of individuals deceased for more than 50 years.) Authorization from the personal representative or next of kin, a waiver or alteration of the Authorization, and/or a data use agreement are not required by HIPAA in order to use decedent PHI.

Use of decedent health information does not require CPHS review and approval if it has been de-identified before receipt by the researchers or does not meet the definition of PHI, as described in the sections above. However, if the study involves the researchers having direct access to decedent medical records or PHI, even if identifiers will not be recorded by the researchers, an application must be submitted for CPHS review and approval.

Before releasing decedent PHI, the covered entity must obtain from the researcher: (1) oral or written representations that the use and disclosure is sought solely for research on the PHI of decedents; (2) oral or written representations that the PHI for which use or disclosure is sought is necessary for the research purposes; and (3) documentation of the death of the individuals whose PHI is sought by the researchers.

D. Training

Researchers who plan to use PHI are subject to the requirements of HIPAA and must complete the HIPAA Research Training before their CPHS protocol will be approved.

- **HIPAA Research Training:** [Online Tutorial Assessment on Research Aspects of HIPAA](#)

E. Additional Information

For additional information on research and HIPAA, please visit the links below and/or contact the Office for Protection of Human Subjects.

- [DHHS HIPAA website](#)
- [DHHS OCR Summary of the HIPAA Privacy Rule](#)
- [NIH HIPAA Privacy Rule website](#)
- [University of California HIPAA website](#)
- [State of California Office of Health Information Integrity](#)
- [UC System Position Paper on Research-Related Health Information](#)
- [For HIPAA-related definitions see CPHS/OPHS Glossary](#)

For other HIPAA related questions, please contact the Berkeley Campus Privacy Office at privacyoffice@berkeley.edu.