



HIPAA and Research

Responsible Officer:	SVP - Chief Compliance & Audit Officer
Responsible Office:	EC - Ethics, Compliance & Audit Services
Issuance Date:	1/30/2014
Effective Date:	1/30/2014
Scope:	This policy applies to all individuals who utilize Protected Health Information for research purposes.

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I. POLICY SUMMARY

The University of California (UC) utilizes Protected Health Information (PHI) for research in a manner that respects human subjects' privacy in accordance with the Privacy Rule promulgated under the Health Insurance Portability and Accountability Act (HIPAA) and other applicable laws. Under the Privacy Rule, when a researcher at UC wants to utilize PHI in order to conduct research, the researcher must (1) obtain the authorization of the subject whose PHI he or she wants to utilize or (2) satisfy a specific exception to the Authorization requirement. It is important to keep in mind that when a researcher is designing and conducting a study that involves the utilization of PHI from the Single Health Care Component (SHCC), he or she must access only the minimum information necessary to conduct the study.

II. DEFINITIONS

"Utilize" includes, for purposes of this policy, "receive," "create," "store," "access," "share," "use," and "disclose."

Please refer to the UC HIPAA Glossary and the IS-3 policy for other definitions.

III. POLICY TEXT

A. RESEARCH USE OF PROTECTED HEALTH INFORMATION (PHI)

A researcher who seeks to utilize Protected Health Information without written Authorization that complies with the specific requirements of HIPAA must limit his or her request to the minimum information necessary to conduct the research.

Conditions when PHI may be utilized for Research Purposes

SHCC PHI may be utilized for research purposes under one or more of the following conditions, which are described in more detail, below:

1. **Individual Subject's Authorization:** After obtaining the individual subject's (or legally authorized representative's) authorization using the UC HIPAA Research Authorization form. A decision to use an alternative form that complies with the standards of a valid HIPAA Authorization can be made at the campus level if the campus adopts a policy standard specifying a required approval process for use of the alternative form;
2. **Waiver of Authorization:** After obtaining a waiver of Authorization from any duly constituted IRB or Privacy Board (duplicative review is not required);
3. **Limited Data Set & Data Use Agreement:** By using a Limited Data Set, subject to a Data Use Agreement;
4. **Deidentified Data:** After the PHI has been deidentified; or
5. **Activities Preparatory to Research/Research on Decedent:** After making certain representations to the appropriate organizational unit of the SHCC when utilizing PHI preparatory to research or PHI about a deceased individual.

Note: *compliance with these conditions is not in lieu of any IRB or other committee reviews required under a campus' human research protections program.*

1. **Individual Subject's Authorization**

If Authorization is obtained from individual subjects, or their representatives, for utilization of their PHI for research purposes, the official UC HIPAA Research Authorization form titled "Permission to Use Health Information for Research," or an Authorization form approved by the researcher's campus must be used. This form is *in addition to* an Informed Consent Form. The Informed Consent Form and the HIPAA Authorization may also be combined with the appropriate approvals at the campus level.¹

When a research project with multiple activities that the subject can participate in, a single Authorization form for the utilization of PHI for the multiple activities can be used.

¹ For a combined form this will be the IRB and possibly the Privacy Officer, Compliance Officer and/or other parties.

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It must be clear to the subject those components for which the Authorization is required before they can participate (such as a clinical study) versus those components that are optional (such as data or tissue banking).

For example, research may include both a clinical study component and the banking of tissue and associated PHI. The subject will be required to sign an Authorization for utilization of his or her PHI in order to receive the research-related service (a "conditioned authorization"); but he or she does not need to authorize his/her PHI to be utilized in the tissue banking component of the research in order to participate in the clinical study ("unconditioned authorization").

An Authorization form combining conditioned and unconditioned components of the research may be used, provided that the Authorization clearly differentiates between the conditioned components (e.g., utilization of PHI that is *necessary* in order for the subject to participate in a clinical study) and unconditioned components (e.g., those components for which subjects are not required to allow the utilization of their PHI in order to participate in the clinical study); and clearly allows the subject the option to participate in the unconditioned research activities. The UC HIPAA Research Authorization form can be found at: <http://www.ucop.edu/ethics-compliance-audit-services/compliance/hipaa/hipaa-authorization-forms.html>

2. Waiver of Authorization

- (a) Review of Requests for Waiver of Authorization - A UC or other IRB or Privacy Board functioning under a Federalwide Assurance or in compliance with HIPAA may, during a convened meeting or using expedited procedures, grant a request for a waiver of authorization under certain circumstances (see below for waiver criteria). Partial waivers may be granted for limited circumstances, such as subject recruitment. Campuses may, but are not required to, rely exclusively on local or UC IRBs or Privacy Boards.
- (b) Privacy Boards - An IRB may be assigned to review researcher requests for waivers of Authorization. Alternatively, organizational units of the SHCC may designate a Privacy Board to perform the same responsibilities and other functions. If a Privacy Board is used it must:
- (1) Have members with varying backgrounds and appropriate professional competency as necessary to review the effect of research protocols on individuals' privacy rights and related interests;
 - (2) Include at least one member who is
 - not affiliated with UC,
 - not affiliated with any entity conducting or sponsoring the research, and
 - not related to any person who is affiliated with any of such entities (Unaffiliated); and

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- (3) Not permit any member to participate in a review of any project in which the member has a conflict of interest.
 - (4) Conduct its activities through convened meetings at which a majority of members, including at least one who is Unaffiliated, are present; or through an expedited process consisting of a review by the Chair or his or her designee.
- (c) Elements of a Waiver of Authorization - In order to approve a waiver of Authorization, the IRB or Privacy Board must determine and document that:
- (i) The utilization of PHI presents no more than a minimal risk to the privacy of the subject, based on, at least, the presence of the following elements:
 - (a) An adequate plan to protect identifiers from improper utilization (note: the IRB or Privacy Board must be cognizant of and should consider the requirements of the HIPAA Security Rule if the information is maintained in electronic form);
 - (b) An adequate plan to destroy the Identifiers at the earliest opportunity consistent with 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
 - (c) Adequate written assurance 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 project, or for other research for which the utilization of PHI would be permitted by HIPAA;
 - (ii) The research could not practicably be conducted without the waiver; and
 - (iii) The research could not practicably be conducted without access to and utilization of the PHI
- (d) Documentation of a Waiver of Authorization - Once a waiver has been approved, in order to access the PHI for which the waiver was approved, the researcher must maintain (or have access to) and be prepared to provide to the data steward, either in paper or in electronic format, documentation that contains the following:
- (1) The date on which the IRB or Privacy Board approved a waiver of Authorization;
 - (2) A statement that the IRB or Privacy Board has determined that the waiver of Authorization satisfies the three waiver criteria referenced in **items (i), (ii), and (iii) of paragraph c above**;
 - (3) A brief description of the PHI to which the IRB or Privacy Board approved access;
 - (4) A statement regarding whether the waiver of Authorization was approved under a normal or an expedited review process; and,
 - (5) The written or electronic signature of the IRB or Privacy Board Chair or the Chair's designee.

3. Limited Data Set and Data Use Agreement

The SHCC may utilize a Limited Data Set (LDS) for research purposes, provided a Data Use Agreement (DUA) is executed with the recipient of the LDS. A waiver of Authorization is not required.

(a) Limited Data Set (LDS)

A Limited Data Set is PHI that excludes the following direct Identifiers of the individual or of relatives, employers, or household members of the individual:

- (1) Names;
- (2) Postal address information, other than town or city, State, and zip code;
- (3) Telephone numbers, fax numbers, electronic mail addresses;
- (4) Social security numbers, medical record numbers, health plan beneficiary numbers, account numbers, certificate/license numbers, vehicle identifiers and serial numbers (including license plate numbers);
- (5) Device identifiers and serial numbers;
- (6) Web Universal Resource Locators (URLs), Internet Protocol (IP) address numbers;
- (7) Biometric identifiers, including finger and voice prints; and
- (8) Full face photographic images and any comparable images.

(b) Data Use Agreement (DUA)

In order to use or disclose an LDS for research purposes, the SHCC must enter into a Data Use Agreement (DUA) with the recipient of the LDS, even if the recipient is a UC employee. The DUA must be signed on behalf of The Regents of the University of California, and by the recipient.

Every DUA must include the following elements:

- (1) Establish the permitted uses and disclosures of the LDS by its recipient (limited to research, public health, or health care operations). The DUA may not authorize the LDS recipient to use or further disclose the information in a manner that would violate the requirements of the Privacy Rule, if done by the SHCC;
- (2) Establish who is permitted to use or receive the LDS; and
- (3) Provide that the LDS recipient will:
 - (i) Not use or further disclose the information other than as permitted by the DUA or as otherwise required by law;

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- (ii) Use appropriate safeguards to prevent utilization of the information other than as provided for by the DUA (in other words, comply with the requirements of any UC and/or campus level policy on the protection of the information);
- (iii) Report to the SHCC any utilization of the information not provided for by its DUA of which it becomes aware;
- (iv) Ensure that any agents, including a subcontractor, to whom it provides the LDS, agrees to the same restrictions and conditions that apply to the LDS recipient with respect to such information and that such agreement is documented by the recipient and agent or subcontractor; and
- (v) Not identify the information or contact the individuals.

If any individual at UC becomes aware of a pattern of activity or practice of the LDS recipient that constitutes a material breach or violation of a UC DUA, that individual must immediately report it to the local Compliance Officer or HIPAA Privacy Officer.

4. Deidentified Data

A researcher may utilize a deidentified data set without a subject's Authorization. Data is considered to be deidentified only if:

- (a) A person with appropriate knowledge of and experience with generally accepted statistical and scientific principles and methods for rendering information not Individually Identifiable:
 - (1) Determines, applying such principles and methods, the risk that the information could be used by an anticipated recipient, alone or in combination with other reasonably available information, to identify an individual who is a subject of the information, is very small; and
 - (2) Documents the methods and results of the analysis that justify such determination; OR
- (b) The following Identifiers of the individual or of **relatives, employers, or household members of the individual**, are removed:
 - (1) Names;
 - (2) All geographic 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:
 - (3) The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and

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- (4) The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people are changed to 000.
 - (5) 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;
 - (6) Telephone numbers;
 - (7) Fax numbers;
 - (8) Electronic mail addresses;
 - (9) Social security numbers;
 - (10) Medical record numbers;
 - (11) Health plan beneficiary numbers;
 - (12) Account numbers;
 - (13) Certificate/license numbers;
 - (14) Vehicle identifiers and serial numbers, including license plate numbers;
 - (15) Device identifiers and serial numbers;
 - (16) Web Universal Resource Locators (URLs);
 - (17) Internet Protocol (IP) address numbers;
 - (18) Biometric identifiers, including finger and voice prints;
 - (19) Full face photographic images and any comparable images; and
 - (20) Any other unique identifying number, characteristic, or code, except as permitted by paragraph (c) of this section; and
- (c) The SHCC does not have actual knowledge that the information could be used alone, or in combination with other information, to identify an individual who is a subject of the information.²

Re-identification. An organizational unit of the SHCC, other than the researcher, may assign a code or other means of record identification to allow deidentified information to be re-identified by the SHCC, provided that:

- (a) *Derivation.* The code or other means of record identification is not derived from or related to information about the individual and is not otherwise capable of being translated so as to identify the individual; and

² This list addresses HIPAA law only please review state law requirements.

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(b) *Security.* The SHCC does not use or disclose the code or other means of record identification for any other purpose, and does not disclose the mechanism for re-identification.

Note: *encryption of data is not the equivalent of deidentification.*

5. Activities Preparatory to Research

A researcher may utilize PHI to support activities preparatory to research if the researcher first represents to the appropriate organizational unit of the UC SHCC that:

- (a) Utilization is sought solely to review PHI as necessary to prepare a research protocol or for similar purposes preparatory to research;
- (b) No PHI is to be removed from the SHCC by the researcher in the course of the review; and
- (c) The PHI for which use or access is sought is necessary for the research purposes.

Note: *HIPAA requires covered entities like UC to create adequate separation (i.e., “firewalls”) between those components covered by HIPAA (“covered components”) and those components that are not (“non-covered components”). At UC, research activities that do not include the delivery of or payment for clinical care or that are not performed at or within a UC clinical facilities are outside the covered component. A review preparatory to research that involves the transfer of PHI from the SHCC to UC’s research component is prohibited by HIPAA. However, a researcher may access PHI within the SHCC if it is not removed physically or electronically.*

6. Research on Decedent Information

Research on individuals who are deceased is not considered human subjects research under the Common Rule. The SHCC may disclose PHI about a deceased individual to a researcher, without any other approvals, so long as the researcher provides to the SHCC:

- (a) Representation that
 - (1) the utilization is solely for research that involves the PHI of decedents;
 - (2) the PHI is necessary for research purposes; and
- (b) At the request of the SHCC, documentation of the death of such individual.

B. ACCOUNTING FOR DISCLOSURES FOR RESEARCH PURPOSES

Patients who are also study subjects have the right to receive an accounting of certain disclosures made of their PHI done without their written authorization.³ Detailed information on the requirements for accounting for disclosures may be found in the UC HIPAA Patients' Rights policy. Researchers are responsible for coordinating with the responsible party within the SHCC on their campus. Researchers will need to assure they are able to provide all the requisite data elements required for a valid accounting for the disclosure.

C. RESEARCH DATABASES

1. Creation of Databases for Research Purposes

All of the requirements of the Privacy Rule apply to the disclosure of PHI for the creation of a database primarily for research purposes. In other words, the researcher must do one of the following before utilizing the PHI to create the database:

- (1) secure the patient's (or legally authorized representative's) Authorization (either alone or in combination with a clinical study Authorization, as further provided above), or
- (2) obtain a waiver of Authorization from an IRB or Privacy Board; or
- (3) obtain a Limited Data Set with a Data Use Agreement; or
- (4) obtain a Deidentified Data set; or
- (5) create the database using information gathered only from decedents.

2. Use of An Existing Clinical Database for Research Purposes

All of the requirements of the Privacy Rule apply to utilization of PHI contained in any database created for clinical services. If the information is accessed for a research purpose, this is a "disclosure" from the SHCC. Research purpose includes reviews preparatory to research, IRB or Privacy Board approval of the protocol, subject Authorization or waiver of Authorization, etc. If the data in the database are deidentified, as described above, none of the Privacy Rule requirements apply. If the database is created *and* maintained outside the SHCC, *i.e.*, the researcher does not need to utilize PHI to create the database, and the database is not used in any way for clinical care, none of the Privacy Rule requirements apply. Other state law privacy requirements do apply.

³ When a researcher utilizes PHI for his or her study under a waiver of authorization (whether complete or partial), preparatory to research or research on decedents it is a disclosure by the SHCC and must be accounted for by the SHCC.

D. CLINICAL STUDIES

1. The Patient's Right to Access PHI Created in a Research Study

A research subject who is also a patient has the right to access PHI created during the research study and maintained in the SHCC's Designated Record Set. However, the researcher may independently suspend the subject's right to access the PHI while the study is in progress, so long as the subject agrees in writing to such denial of access when authorizing utilization of his or her PHI to participate in the study. The researcher must inform the subject in the Authorization form that access to PHI in the Designated Record Set will be reinstated at the conclusion of the research study. Information maintained in a *research record*, and not within a medical record system, would not be considered PHI and thus not subject to the right to access under HIPAA (though it may be subject to access rights under other state laws). However, results of study services and other information maintained in the patient/participant's Designated Record Set (which includes the medical record) would be subject to the right to access.

2. Compliance and Oversight Activities

A subject's Authorization is not required for the SHCC to disclose PHI in order to report adverse events to regulatory, legal and compliance committees and units (e.g., IRB, Risk Management, Legal Counsel), the SHCC, the federal Office for Human Research Protections, the FDA and other governmental agencies or entities as required by law, regulations, or UC policy, or research sponsors or other entities responsible for the product under investigation in support of activities related to the quality, safety, or effectiveness of their products. Although the subject's Authorization is not required, the Authorization form should advise the subject of the possibility of such disclosures. Otherwise, the disclosures are subject to the accounting requirement described in Section B above.

E. PAYMENT FOR DATA COLLECTION

If a payer (e.g., sponsor) compensates the UC **primarily** to supply data, then that disclosure may constitute a sale of PHI and the researcher should contact his/her local Privacy Officer.

If, however, the provision of PHI is a byproduct of the service to the payer, then that disclosure does not constitute a sale of PHI and no separate Authorization for the sale would be required. For example, if the SHCC receives grant funding to perform a research study and, as part of that study, the SHCC provides individually Identifiable Health Information to the sponsor, a separate, written Authorization **for the sale of PHI** would not be required (but, absent a waiver, Authorization **for disclosure of PHI** to the sponsor is required). Further, the receipt of grant funding from a government agency to conduct a program is not a sale of PHI, even if, as a condition of receiving the funding, the SHCC is required to report PHI to the agency for program oversight or other purposes. In either case, you should consult your local Privacy Officer for a case-specific analysis.

IV. PROCEDURES

V. RELATED INFORMATION

- [UC HIPAA Glossary](#)
- [HIPAA-2: HIPAA Administrative Requirements](#)
- [HIPAA-6: HIPAA Patients Rights](#)

VI. FREQUENTLY ASKED QUESTIONS

Not Applicable

VII. REVISION HISTORY

This policy was originally issued on 01/30/2014.