

HIPAA and Research at UC

The University of California is a hybrid covered entity with a single health care component (SHCC) that performs multiple functions covered by HIPAA.

Research at the University of California is not a covered function under the HIPAA Privacy Rule. UC's employees/workforce members, when acting solely in their capacity as researchers, are not considered a part of the SHCC. However, when a UC researcher is also a health care provider or a member of a medical center's workforce, the Privacy Rule applies to the researcher's activities, and he or she must comply with all requirements of the Privacy Rule.

Therefore, when a researcher conducting research pursuant to an IRB-approved protocol wants to obtain Protected Health Information (PHI) from records maintained by the SHCC (such as those found in a hospital's medical records department), the Privacy Rule requires that the SHCC receive assurances from the IRB, Privacy Board, and/or researcher that either:

- a) the subject has authorized the use of PHI for research;
- b) the IRB or Privacy Board has waived the research authorization based on specific waiver criteria; or
- c) the researcher is requesting only a limited or de-identified set of information.

Once PHI is released by the SHCC to the researcher, it is no longer protected under the Privacy Rule. However, under California law (Confidentiality of Medical Information Act, CMIA, Cal.Civil Code Sec 56 – 56.16) certain redisclosures of medical information beyond HIPAA boundaries must be authorized.

Research Related Health Information—RHI

The University of California employs the term "Research Related Health Information" (RHI) to identify types of data used in research that would be personally identifiable but not considered PHI. RHI shares some characteristics with HIPAA PHI, but 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.

Research *Use* of Medical Records

Research studies that *use* medical records as a source of personally identifiable research data are using PHI. In order to use PHI, the researcher must comply with the Privacy Rule and with IRB or Privacy Board requirements.

Research *Creation* of Medical Records

A researcher *creates* PHI as a product of the research when engaged in interventional clinical studies where treatments are being compared for safety and effectiveness in a setting where services are billed to insurers. In order to participate in such treatments, the subject must consent to participate and must authorize release of PHI. All such PHI should be included in the subject's medical record maintained by the SHCC. In contrast, a research study that does not include a diagnostic or therapeutic intervention and does not acquire health-related facts about a person or PHI from the either the SHCC or a covered health care provider or

the University self-insured health plan creates information that, if individually identifiable, would be considered RHI, not PHI.

When PHI and RHI are Combined

When RHI and PHI are both found in a research project, it may become impossible to determine the source and use of a particular item of information or data. In these cases the researcher should apply Privacy Rule standards to protect identifiable information if even a fraction of the research records use or derive PHI.

Two Hats—Covered Provider and Researcher

A member of the UC workforce may serve dual roles as both a covered provider under the Privacy Rule and as a researcher not covered by the Privacy Rule. A researcher is a covered provider if he or she furnishes health care services to individuals, including the subjects of research, in a part of the organization that bills for care. The individual researcher has a responsibility to understand when his or her activities are covered by the Privacy Rule and must comply with the requirements of the Privacy Rule and of the University's HIPAA policies.

Business Associate Agreement

Research is not a covered function at UC. Business associate agreements only apply to HIPAA-covered functions. Therefore, the disclosure of PHI to a researcher does not require a business associate agreement.

Obtaining PHI for Research

If a University researcher wants to obtain an individual's PHI from the University's covered health care provider or health plan, the researcher must obtain IRB approval and must either:

- Provide the SHCC with copies of the IRB's approval and Research Authorization forms; or
- Provide the SHCC with a copy of the IRB's Waiver of Authorization; or
- Provide the SHCC with the IRB's approval for research using a Limited Data Set or Deidentified Data Set. For purposes of creating the Data Sets, the SHCC may determine that the researcher is a member of the SHCC workforce providing business-type services to the covered entity, e.g., creating a data set, and may have access to the information necessary to create the Limited or Deidentified Data Set;
- Provide the SHCC and/or other covered entities evidence that the requirements for decedent research have been met.

In all cases except data set creation, the investigator must assure that only the minimum necessary information is being requested and that any PHI created in the course of the research is entered into the medical record or Designated Record Set.

Disclosure of PHI for Research Purposes with the Individual's Signed Research Authorization

When the IRB has approved a research protocol that requires the subject's informed consent and PHI is needed for the study, the subject must also sign a Research Authorization. The UC Research Authorization is constructed to comply with both HIPAA and the Confidentiality

of Medical Information Act. HIPAA and the CMIA define protected health information differently and contain different rules concerning subject authorization to release health information for research. Please refer to the University-approved authorization form Permission to Use Personal Health Information for Research. When providing the researcher with the PHI described in the Authorization, the SHCC must be able to reasonably rely that the PHI requested is the minimum necessary for the study.

Disclosure of PHI for Research Purposes That Do Not Require an Individual's Authorization

The SHCC may disclose PHI to a researcher without patient Authorization as follows:

1. IRB or Privacy Board approved and certified Waiver of Authorization; or
2. IRB or Privacy Board approved protocol using a Limited Data Set and with a Data Use Agreement between the researcher and SHCC; or
3. IRB Approved Preparation of a Research Protocol; or
4. Research on PHI of Decedents; or
5. IRB or Privacy Board approved protocol using Deidentified Data.

The Minimum Necessary Standard applies to the request for and disclosure of PHI in these circumstances.

Waiver of Authorization

To use or disclose PHI with an IRB or Privacy Board approved Waiver of the individual's Authorization, the SHCC must receive from the researcher requesting the disclosure of PHI an IRB or Privacy Board Letter of Approval that certifies all of the following:

1. Identification of the IRB and the date on which the Waiver of Authorization was approved;
2. A brief description of the PHI for which use or access has been determined to be necessary by the IRB or Privacy Board;
3. A statement that the Waiver of Authorization has been reviewed and approved under either normal or expedited review procedures as required under the Common Rule. An expedited review process permits the SHCC to accept an IRB's documentation of Waiver of Authorization when only one member of the IRB has conducted the review.
4. The signature of the IRB Chair or other member, as designated by the IRB Chair, that certifies the Waiver of Authorization; and
5. A statement that the IRB has determined that the Waiver of Authorization, in whole or in part, satisfies the three waiver criteria in the Privacy Rule:
 - a. The use or disclosure of PHI involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements:
 - i. An adequate plan to protect the identifiers from improper use and disclosure;
 - ii. 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

- iii. 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 project, or for other research for which the use or disclosure of PHI would be permitted by this subpart;
- b. The research could not practicably be conducted without the waiver or alteration;
and
- c. The research could not practicably be conducted without access to and use of the PHI.

The IRB must document and retain copies for six years of all information that demonstrates that the Waiver of Authorization criteria were met. The SHCC must document and retain copies for six years of all IRB Letters of Approval certifying Waiver of Authorization. The SHCC must provide an accounting to the subject of any disclosures of PHI provided with a Waiver of Authorization.

Preparatory to Research

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 or exemption by an authorized IRB.

In order for the SHCC to allow a researcher access to PHI to prepare a research protocol, the researcher must provide to the SHCC written representation in the form of an IRB approval or exempt registration letter that the following criteria are met:

1. The researcher will not remove any PHI from the SHCC; and
2. The use or disclosure of the PHI is permitted by the IRB as an activity described in an IRB approved or exempted research protocol (format to be determined by local IRB).