HIPAA Privacy Rule RES-301: Uses and Disclosures of Protected Health Information for Research Purposes

I. Policy

Federal and state regulations govern the protection of human subjects in research.[1] While these regulations provide for some patient confidentiality protections, the HIPAA Privacy Rule adds additional privacy protections for human subjects and establishes the conditions under which protected health information ("PHI")[2] may be used or disclosed by the University of Southern California (USC)[3] for research purposes.

If a researcher is accessing, using or obtaining a research participant's identifiable health information (e.g., medical records, mental health information, lab reports, x-rays, tissue samples) from a health care provider (e.g., physician or other healthcare practitioner, hospital, clinic, nursing home) or health plan that is governed under the HIPAA privacy federal regulations, then the researcher will be required to meet one of the following:

- The research participant whose PHI is requested has signed a HIPAA-compliant authorization permitting the release of such health information as described in Section II.A. A health care provider who also is the researcher still must obtain an authorization from the subject before the provider can use PHI for research purposes.
- The IRB has waived the need for a HIPAA authorization as described in Section II.B.
- The health information has been de-identified as described in Section II.C.
- The information is used or released in a limited data set and the researcher has signed a data use agreement, as described in Section II.D.

[1] 45 CFR Section 46 et al; California Health and Safety Code Section 24170 et seq.

[2] Protected Health Information is identifiable information that relates to an individual's past, present or future physical or mental condition or to payment for health care. The term Protected Health Information does not include identifiable information that relates to a person who has been deceased for more than 50 years or health information that has been de-identified as described in this policy.

[3] For purposes of the HIPAA Privacy Rule, USC includes those entities that comprise Keck Medicine of USC, including but not limited to, USC Norris Cancer Hospital, Keck Hospital of USC, USC's employed physicians, nurses and other clinical personnel, those units of USC that provide clinical services within the Keck School of Medicine, School of Pharmacy, the Herman Ostrow School of Dentistry, Physical and Occupational Therapy as well as the Keck Doctors of USC, USC Care Medical Group, affiliated medical foundations of Keck and their physicians, nurses and clinical personnel, USC Verdugo Hills Hospital, its nurses and other clinical personnel, Verdugo Radiology Medical Group, Verdugo Hills Anesthesia, and Chandnish K. Ahluwalia, M.D., Inc. and those units that support clinical and clinical research functions, including the Offices of the General Counsel, Audit and Compliance.

- The health information is used or released preparatory to research or the researcher is conducting research on decedents' health information and the researcher has signed a certification as described in Section II.E.
- The health information is released to the FDA as described in Section II.F.

As described below, USC may receive a reasonable, cost-based fee to cover the costs to prepare and transmit PHI for research purposes, but USC may not otherwise sell PHI for research purposes without a HIPAA authorization from the individual whose PHI is requested.

All USC faculty members and other study personnel who use protected health information in the course of conducting their research MUST complete an educational program about the HIPAA Privacy Rule. The program can be accessed through the USC Office of Compliance website at www.usc.edu/compliance. Please refer to USC HIPAA Privacy Policy GEN-101 *Education of Covered Workforce* for more details.

II. Procedures

A. Signed HIPAA Compliant Authorization

1. USC Form Authorization

USC has developed a template HIPAA-compliant authorization, which should be obtained from research participants at the time that informed consents are obtained. The document entitled "HIPAA AUTHORIZATION TO USE HEALTH INFORMATION FOR RESEARCH" is available on the USC policy and IRB websites. No modifications should be made to the template without approval from the USC Office of Compliance. The IRB also must be notified of any and all modifications approved by the USC Office of Compliance.

a. The IRB and compliance office will determine those circumstances when authorizations may provide for use of health information for future unspecified research purposes, which must consider, among other things: (i) that the future purpose is adequately described so that the research participant can reasonably expect that his/her PHI could be used or released for future research; (ii) that use or release of any sensitive health information is adequately explained; and (iii) any PHI collected beyond the timeframe of the current study and used or released for future research is described.

b. There are certain circumstances when conditional (i.e., the participant must agree as a condition to participating in the research) and non-

conditional research components may be combined. Please consult with the compliance office for further information.[4]

2. Authorizations Requiring Submission to the IRB

For new protocols and continuing review applications submitted to the IRB, Investigators should include the "HIPAA AUTHORIZATION TO USE HEALTH INFORMATION FOR RESEARCH" with the informed consent document and other application documents.

3. Authorization May Still Be Needed

For waived research that does not require an Informed Consent (e.g., retrospective records research), a HIPAA authorization may still be required unless an exception to the authorization requirement, as set forth in Section II.B.2, is satisfied.

4. Interaction with the Provider

The signed HIPAA authorization should be provided to the applicable health care provider when a request is made for the provider to release protected health information relating to the research subject.

5. Document Retention

Copies of the Authorizations or waivers should be maintained in the relevant research files.

6. Revocation of HIPAA Authorization

A research participant's partial revocation of a future research use or unconditional research component will not result in a revocation of the complete HIPAA authorization. If it is not clear, however, USC must obtain a written clarification from the research participant to determine whether the revocation is partial or complete. If the participant does not provide a clarification, the revocation will be deemed a complete revocation.

[4] Research participants must opt-in (e.g., check a box) to agree to any unconditional research components. If it is determined that that the unconditional components should be detailed in a separate document, that separate document must be cross-referenced in the authorization. The template HIPAA authorization may not be combined with a notice or consent that serves a separate purpose other than to authorize the use or disclosure of PHI (e.g., informed consent form).

B. Waiver of HIPAA Authorization

1. Responsibility for Determination

The USC IRB is solely responsible for determining if a research study qualifies for a waiver of the HIPAA authorization. A research study must meet the criteria in Section II.B.2 below to obtain a waiver of HIPAA authorization.

2. Criteria for Waiver of Authorization

a. The USC IRB may approve a waiver of the authorization requirement only if it can document that the following criteria for the waiver have been met:

i. The use or disclosure of protected health information involves no more than minimal risk to the individuals or their privacy, based on

- An adequate plan to protect identifiers from improper use and disclosure,
- An adequate plan to destroy the identifiers at the earliest opportunity (unless there is a health or research justification for retaining identifiers or such retention is otherwise required by law), and
- Adequate assurances that the protected health information 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 permitted under this policy;

ii. The research could not practicably be conducted without the alteration or waiver; and

iii. The research could not practicably be conducted without access to and use of the protected health information.

b. The USC IRB shall include in the waiver approval document the following:

i. A brief description of the protected health information for which use or access has been determined to be necessary by the IRB. This description will be based on the data

collection form submitted by the investigators, indicating the health information to be used or accessed;

ii. A statement that the alteration or waiver of authorization has been reviewed and approved by the IRB under normal or expedited procedures;

iii. The signature of the Chair or other member, as designated by the Chair, of the IRB; and

iv. Date of the approval.

3. Procedure for Obtaining Waiver

The iStar application includes a section for investigators requesting a HIPAA authorization waiver. Investigators must provide sufficient information to satisfy the above criteria if they intend to seek a waiver of HIPAA authorization. If these criteria are not satisfied, the IRB will not approve the request for a waiver of HIPAA authorization.

4. Interaction with the Provider

The IRB approved waiver should be provided to the applicable health care provider when a request is made for the provider to release protected health information relating to the research participant.

5. *Accounting of Disclosures*

USC must account for the following disclosures of PHI for research purposes:

a) Pursuant to IRB approved waiver of the HIPAA authorization
b) Pursuant to an Investigator certification that the use of PHI is "preparatory to research"
c) Pursuant to an Investigator certification that he/she is conducting decedent research

6. Protected Health Information that cannot be obtained with an IRB approved HIPAA Waiver of Authorization

a. HIV Test Results

California law requires patient authorization for a provider's disclosure of a patient's HIV test results. State law does not provide an exception from this requirement for an IRB waiver of the authorization requirement. Accordingly, a health care provider cannot release HIV test results to a researcher unless a patient has signed a HIPAA-compliant authorization. See USC HIPAA Privacy Policy CLIN-203 *Special Privacy Considerations* for more details.

b. Substance Abuse Records

Medical records that contain information pertaining to alcohol or drug treatment protected under federal law may not be disclosed for research purposes unless: (1) the patient has provided specific authorization for the use and release of that information; or (2) the program director at the treatment facility provides written authorization as required under federal law. See USC HIPAA Privacy Policy CLIN-203 *Special Privacy Considerations* for more details.

c. Psychotherapy Notes

Psychotherapy notes recorded by a mental health provider documenting or analyzing the contents of conversation with an individual or group counseling, and which are kept separate from the rest of the medical record, are protected under HIPAA and may not be disclosed for research purposes unless a patient has signed a HIPAA Authorization and specifically agreed to that release of information. See USC HIPAA Privacy Policy CLIN-203 *Special Privacy Considerations* for more details.

C. De-identification

A USC researcher is not required to satisfy the authorization requirement if the health information is de-identified. See USC HIPAA Policy GEN-105.

1. Procedures for De-identification

A USC researcher who desires to use de-identified PHI from another covered entity (e.g., LAC+USC Medical Center, Childrens Hospital of

Los Angeles) may obtain the PHI, perform the de-identification, and then use the de-identified information for research so long as there is a business associate agreement[5] between USC and that covered entity that contemplates USC providing de-identification services on behalf of the covered entity.[6] The researcher must return or destroy the information that includes the direct identifiers once the researcher has created the de-identified information. USC researchers de-identifying USC PHI may perform this function, as a health care operation on behalf of USC.

D. Limited Data Set

1. *USC researcher may use PHI in a limited data set for research purposes in accordance with this policy.*[7]

a. A limited data set must not include direct or facial identifiers like name, social security number, full-face photos or medical record number.
b. A "limited data set" may include, however, zip codes, dates of service, dates of birth and death and geographic information.

2. *Data Use Agreement*

The individual investigator must execute a Data Use Agreement with USC, which identifies and limits the permitted uses of the information, restricts who can use the data, and requires the recipient to agree not to re-identify the data or contact the individual. USC's form Data Use Agreement is available at https://policy.usc.edu/hipaa/. Requests to use a limited data set must be submitted to the IRB and must specify the data elements to be used. USC HIPAA Policy GEN–104 *Limiting Uses and Disclosures of Protected Health Information to the Minimum Necessary* applies to uses of limited data sets for research purposes.

E. Purposes Preparatory to Research and Decedent Research

1. *Preparatory to Research*

[5] See USC HIPAA Policy BUS–701 *Policy Regarding Business Associates.*

[6] De-identification of PHI constitutes health care operations (See USC HIPAA Policy CLIN–201), and can therefore be performed directly by a covered entity, or by a business associate acting on the covered entity's behalf. The individual de-identifying the PHI as a business associate may also be the intended recipient of the data.

[7] A limited data set also may be used for public health and health care operations purposes provided recipient of the information signs a Data Use Agreement and otherwise complies with this policy.

Protected health information may be used by or disclosed to a researcher as necessary to prepare a research protocol or for similar purposes preparatory to research (e.g., subject recruitment, proposal hypothesis testing) to the covered entity that holds the PHI only if all of the following apply: (i) the use or disclosure is sought solely for purposes that are preparatory to research, (ii) no protected health information will be removed from the entity's premises by the researcher in the course of the review, and (iii) the protected health information for which use or access is sought is necessary for the research purposes. THIS IS A LIMITED EXCEPTION. A researcher may not rely on this exception to access Protected Health Information held by healthcare providers outside of USC (e.g., LAC+USC Medical Center, Children's Hospital of Los Angeles) for recruiting purposes, for example, because using Protected Health Information held by a separate covered entity would be considered a removal from the entity's premises.

2. *Decedents Research*

Protected health information may be used by or disclosed to a researcher for research on decedents who have been deceased less than 50 years, provided the researcher: (i) represents to the covered entity that holds the PHI that the use or disclosure is sought solely for research on the protected health information of decedents, (ii) provides to the entity, upon request, documentation of the death of the research subject, and (iii) represents to the entity that the protected health information is necessary for the research. Researchers may use identifiable health information on decedents who have been deceased for more than 50 years, without complying with this section.

3. *Certifications*

USC researchers desiring access to PHI for purposes preparatory to research or for research on persons deceased within the last 50 years must execute a certification that includes the necessary representations. The certification should be provided to the relevant patient records department or similar unit that maintains the records that the researcher wishes to access. ***A copy of the certification should be filed in the subject's patient record***. The USC form certifications for these purposes are available at https://policy.usc.edu/hipaa/.

F. Disclosure to the Food and Drug Administration

A participant's PHI may be disclosed to a person who is subject to the jurisdiction of the Food and Drug Administration (FDA) with respect to an FDA-regulated product or activity for which that person has responsibility, for the purpose of activities related to the quality, safety or effectiveness of such FDA-regulated product or activity, including but not limited to: (i) to collect or report adverse events, product defects or problems, or biological product deviations, (ii) to track FDA-regulated products, (iii) to enable product recalls, repairs, replacement or lookback activities, or (iv) to conduct post marketing surveillance. See 45 C.F.R. §§164.512(b)(1)(iii).

G. Disclosures to Pharmaceutical Companies under State Law

A pharmaceutical company may not require a patient, as a condition of receiving pharmaceuticals, medications, or prescription drugs, to sign an authorization, release, consent, or waiver that would permit the disclosure of medical information that otherwise may not be disclosed under California Civil Code Section 56.10 or any other provision of law, unless the disclosure is for one of the following purposes:

1) Enrollment of the patient in a patient assistance program or prescription drug discount program.
2) Enrollment of the patient in a clinical research project.
3) Prioritization of distribution to the patient of a prescription medicine in limited supply in the United States.
4) Response to an inquiry from the patient communicated in writing, by telephone, or by email.

H. Repositories

All repositories created or maintained for research purposes are subject to this policy. *Placement* of PHI in a repository requires a patient authorization in accordance with USC HIPAA Policy GEN-102 or a waiver of HIPAA authorization in accordance with this policy. *Use* of PHI in such database repository for research purposes may require a *separate* patient authorization or waiver of HIPAA authorization as well. Contact the Office of Compliance or refer to the USC Biorepository Policy for more details at https://policy.usc.edu/biorepositories/.

III. Sale of PHI

USC may not sell PHI, including limited data sets, without a HIPAA authorization from the individual whose PHI is requested. "Sale of PHI" means receiving remuneration from or on behalf of the recipient of the PHI in exchange for the PHI. A sale of PHI would occur if USC is primarily being compensated to supply PHI it maintains as a health care provider. USC may, however, receive a reasonable cost-based fee to cover the cost to prepare and transmit PHI for research purposes. USC may receive payment by a research sponsor to conduct a research study, even if the research results that may include PHI are disclosed to the sponsor in the course of the study. USC may also receive grants, contracts, or other arrangements to perform research services, where the provision of PHI is a byproduct of the service provided.

Additional References

45 C.F.R. §§164.508, 512, 514

Responsible Office
Office of Compliance
http://ooc.usc.edu/
complian@usc.edu
(213) 740-8258

Executed by: **Elizabeth Garrett**
Provost and Senior Vice President, Academic Affairs

Todd R. Dickey
Senior Vice President, Administration

Date issued: July 15, 2014