I. BACKGROUND:

Federal and state regulations govern the protection of human subjects in research. 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”) may be used or disclosed by the University of Southern California (USC) for research purposes.

II. POLICY:

A. Informed Consent. No research involving human subjects may be conducted unless (1) an informed consent to participate in the research study is obtained from the research subject; (2) a waiver of informed consent has been approved by an institutional review board (IRB); or (3) the IRB has determined that the research study is exempt from federal regulations and that an informed consent is not required.

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.

3 For purposes of the HIPAA Privacy Rule, USC is defined as those components/units that provide clinical services within the School of Pharmacy, the School of Dentistry and the Independent Health Professions (e.g., Physical Therapy, Occupational Therapy, Nursing) as well as USC Care Medical Group, Inc., the USC-affiliated faculty practice plan corporations at the Keck School of Medicine, the USC-affiliated faculty practice plan corporations for Physical Therapy and Occupational Therapy, research that involves clinical treatment, and those units that support the clinical functions, such as the Office of the General Counsel and the Office of Audit and Compliance.

4 The USC policies and procedures regarding the protection of human subjects in research can be found at: http://ccnt.hsc.usc.edu/irb/irb.html and http://www.usc.edu/admin/provost/irb/.
B. HIPAA Privacy Rule.

1. General Rule. As a general rule, a health care provider (e.g., physician or hospital) or health plan may not release PHI to a researcher unless the subject whose PHI is requested has signed a HIPAA-compliant authorization permitting the release of such health information. A health care provider who also is the researcher still must obtain an authorization from the subject before the provider can use the PHI for research purposes.

Section III.B. of this policy describes how such an authorization may be obtained from the subject prior to requesting PHI from a provider covered under the HIPAA Privacy Rule.

2. Exceptions. The following are exceptions whereby it is not necessary to obtain an authorization from subjects to use or release their protected health information:

(a) IRB Waiver. The IRB has approved a waiver of the need to obtain a HIPAA authorization pursuant to Section III.C of this policy;

(b) De-identification. The health information has been de-identified in accordance with Section III.D of this policy;

(c) Limited Data Set. The health information is used or disclosed in a limited data set in accordance with a data use agreement and Section III.E of this policy;

(d) Disclosure to the Food and Drug Administration. A subject’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.

(e) Preparatory to Research. 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 that 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 hospital partners 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.

(f) Decedents Research. Protected health information may be used by or disclosed to a researcher for research on decedents 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.

3. HIPAA Training of USC Researchers. 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. Effective April 14, 2003, the IRB will not approve new or continuing proposals for projects that use protected health information unless (a) all investigators of the project and other study personnel who will access PHI have completed USC's HIPAA educational program and (b) the investigators have provided their certificates of completion to the IRB as proof of same and certified that their respective research staff also have completed the program.


a. Grandfathered Informed Consents. Informed Consent documents that were approved by the IRB prior to April 14, 2003 are grand fathered under the HIPAA Privacy Rule, PROVIDED, no new patients are enrolled after April 14 and/or the informed consent is not obtained again for any reason from existing subjects after April 14. According to the HIPAA Privacy Rule, it is not necessary to obtain a HIPAA authorization from subjects enrolled in a study prior to April 14, 2003 unless you need to re-consent those subjects for some other reason.5

---

5 Please note that while the Privacy Rule does not require that an authorization be obtained, a third party provider may still request that the subject sign an authorization before the provider releases the health information.
b. **Grandfathered Waivers of Informed Consent.** Where an IRB has approved a waiver of informed consent for a research protocol (which typically would arise either in the context of records research or emergency research), the researcher may use PHI in accordance with that approved protocol after April 14, 2003 without a patient authorization. Accordingly, if the requirement for informed consent was waived for a research protocol prior to April 14, 2003, neither patient authorization nor a privacy waiver from the IRB is required for activities pursuant to that protocol after April 14, 2003\(^6\).

c. **Grandfathered Waivers for Recruitment/Enrollment.** Where an IRB has approved a waiver of informed consent prior to April 14, 2003, with respect to a protocol to review medical records in order to identify potential enrollment candidates, the researcher may use PHI in accordance with that approved protocol after April 14, 2003 without a patient authorization. In the absence of such an express waiver of informed consent by the IRB, review of records for enrollment purposes after April 14 will need to be accomplished in a HIPAA-compliant manner (i.e., pursuant to patient authorization, or in circumstances that qualify as exceptions to the general rule, as described in Section II.B.2 of this policy).

### III. PROCEDURES:

The processes for obtaining informed consent and a HIPAA authorization are separate but related. Researchers conducting human subjects research and accessing protected health information must comply with IRB policies and procedures as well as the HIPAA privacy regulations.

**A. Process for Obtaining Subject Informed Consent.** Informed Consent is the process by which information is presented to an individual to enable such individual to decide voluntarily whether or not to participate as a research subject. An investigator must comply with the IRB policies and procedures regarding the protection of human subjects. See USC IRB policies and procedures regarding the process for obtaining subject informed consent.

**B. Process for Obtaining a HIPAA Authorization.**

1. **In General.** In addition to informed consent, a health care provider also must obtain an authorization from the research subject before using or releasing health information for research purposes, unless one of the authorization exceptions set forth in Paragraph II.B.2 above applies.

2. **USC Form Authorization.** USC has developed a template HIPAA-compliant authorization, which should be obtained from research subjects at the time that informed consents are obtained. The document entitled,

---

\(^6\) Unless, subsequent to April 14, 2003, the IRB determined that informed consent was now required for the same research protocol; in that event, patient authorization must also be obtained.
"HIPAA AUTHORIZATION FOR USE AND DISCLOSURE OF HEALTH INFORMATION IN A RESEARCH STUDY" is available at www.usc.edu/compliance and http://ccnt.hsc.usc.edu/irb/irb.html. 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.

3. **When Authorization is Required.** If a researcher is accessing, using or obtaining a research subject/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 obtain either (1) a HIPAA compliant authorization from the subject/patient in order for the healthcare provider, health plan or clearinghouse to release identifiable health information for research purposes, or (2) an IRB approved waiver of HIPAA authorization as described below in Section III.C.

The IRB application documents have been revised to assist investigators in determining whether HIPAA authorizations from research subjects are required in order to use or obtain PHI from a health care provider.

4. **Authorizations Requiring Submission to the IRB.** For new protocols and continuing review applications submitted to the IRB after April 14, 2003, Investigators should include the "HIPAA AUTHORIZATION FOR USE AND DISCLOSURE OF HEALTH INFORMATION IN A RESEARCH STUDY" with the informed consent document and other application documents.

5. **Authorizations Not Requiring Submission to the IRB.** For Informed Consent documents approved by the IRB prior to April 14, 2003, Investigators should append the HIPAA authorization as an addendum to their existing informed consents. Investigators ARE NOT REQUIRED to resubmit their informed consent documents and HIPAA authorizations to the IRB in this case until continuing review. However, any modifications to the authorization template must be approved by the USC Office of Compliance and the IRB must be notified of any changes approved by the compliance office.

6. **Authorization May Still Be Needed for Waived Research.** 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 Paragraph II.B.2, is satisfied.

7. **Interaction with the Provider.** The signed HIPAA compliant 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. In cases where the protocol is grandfathered, it should not be necessary to provide a HIPAA authorization to the provider in order to obtain the research subject’s health information.

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

C. Waiver of HIPAA Authorization.

1. Responsibility for Determination. The USC IRB is responsible for determining if a research study qualifies for a waiver of the HIPAA authorization. A research study must meet the criteria in Section III.C.2 below to obtain a waiver of HIPAA authorization. The IRB applications have been revised to assist investigators in requesting a waiver, if appropriate to their study.


(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 (A) an adequate plan to protect identifiers from improper use and disclosure, (B) 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 (C) 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) 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.
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. IRB application Section I has been revised to add a check box to request a "Waiver of HIPAA authorization." In order for the IRB to approve the waiver of the HIPAA authorization, the investigator needs to provide justification by specifically documenting that the criteria set forth in Section III.C.1(a) have been satisfied.

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 subject. In cases where the protocol is grandfathered, it should not be necessary to provide a HIPAA authorization waiver to the provider in order to obtain the research subject’s health information.

5. 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.

(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. 42 C.F.R. Section 2.52
D. 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, Norris Cancer Hospital) 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 between USC and that covered entity that contemplates USC providing de-identification services on behalf of the covered entity. 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.

E. Limited Data Set. A USC researcher may use PHI in a limited data set for research purposes in accordance with this policy. A limited data set must not include direct or facial identifiers like name, social security number, full-face photos or medical record number. A "limited data set" may include, however, zip codes, dates of service, dates of birth and death and geographic information. 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 http://policies.usc.edu. 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.

F. Purposes Preparatory to Research and Decedent Research:

1. In General. PHI may be used by a researcher as necessary for purposes preparatory to research or decedent research so long as the requirements set forth in Paragraph II.B.2(b) or II.B.2(c), respectively, are satisfied.

---


8 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.

9 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.
2. **Certifications.** USC researchers desiring access to PHI for purposes preparatory to research or for decedent research 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 [http://policies.usc.edu](http://policies.usc.edu).

3. **Patient Enrollment Data as a Purpose Preparatory to Research.** Investigators may use information obtained without patient authorization to identify potential enrollment subjects as preparatory to research ONLY if the investigator is a member of the USC workforce AND the PHI used is USC's (and not, for example, a hospital affiliated with USC).

G. **Database Research.** All databases created or maintained for research purposes are subject to this policy. *Placement* of PHI in such a database requires a patient authorization in accordance with USC HIPAA Policy GEN - 102 or a waiver of HIPAA authorization to create and maintain the database in accordance with Paragraph III.C above. *Use* of PHI in such a database for research purposes requires a *separate* patient authorization in accordance with USC HIPAA Policy GEN - 102 or a *separate* waiver of HIPAA authorization for the specific research project in accordance with Paragraph III.C above. USC’s template research authorization contains a provision addressing database research, which should be utilized if the investigator intends to input information collected from a research study into a research database and use it for future research purposes.