**ACCESS TO PROTECTED HEALTH**

**INFORMATION IN CLINICAL RESEARCH**

**PURPOSE AND SCOPE**

This SOP describes the procedures study personnel will use to access Protected Health Information (HIPAA) in accordance with the HIPAA Privacy Rule when a Covered Entity under HIPAA has collected the Protected Health Information. The HIPAA Privacy Rule establishes the conditions under which protected health information may be used or disclosed by covered entities for research purposes.

**APPLICABLE REGULATIONS AND UC POLICIES**

DHHS 45 CFR 164 (Health Insurance Portability and Accountability Act of 1996)

**DEFINITIONS**

Covered Entity. (1) a health plan. (2) A health care clearing house. (3) a health care provider who transmits any health information in electronic form in connection with a transaction covered by HIPPA. All UC physician practice plans are covered entities.

Privacy Rule. Privacy Rule refers to the Standards for Privacy of Individually Identifiable Health Information portion of HIPAA. The Privacy Rule implements the privacy requirements of the Administrative Simplification subtitle of the Health Insurance Portability and Accountability Act of 1996.

Protected Health Information (PHI). Protected health information means individually identifiable health information (with limited exceptions) in any form, including information that is transmitted orally, or in written or electronic form. Examples include patient’s name, address, zip code, birth date, social security number, and telephone number.

Authorization. A written document signed by a patient of a Covered Entity allowing Protected Health Information (PHI) to be shared for purposes specified in the Authorization. The authorization will be developed by the Covered Entity and will have the elements required by HIPAA.

HIPAA. An acronym for the Health Insurance Portability and Accountability Act of 1996. HIPAA establishes national standards for health care transactions, unique health identifiers, code sets for the data elements of the transactions, security of health information, and electronic signature.

**PERSONS RESPONSIBLE**

*Principal Investigator.*

*Clinical Research Coordinator*

*Clinical Research Nurse*

*Data manager*

*Research Assistant*

1. **Accessing Protected Health Information for Research with the Patient’s Authorization**

The HIPAA Privacy Rule permits researchers in Covered Entities to use or disclose Protected

Health Information for research purposes when a research participant agrees to the use or disclosure of his or her information by signing an authorization that satisfies the requirements of 45 CFR 164.508. See Human Research Protection website for HIPAA information (http://researchcompliance.uc.edu/hipaa/) on getting Patient authorization for a research participant’s authorization for clinical trials and for some medical records research. Several special provisions apply to research authorizations:

* An authorization for a research purpose may state that the authorization does not expire, that there is no expiration date or event, or that the authorization continues until the “end of the research study;” and
* An authorization for the use or disclosure of protected health information for research may be combined with consent to participate in the research, or with any other legal permission related to the research study.

1. **Accessing Protected Health Information for Research Without Authorization**

To use or disclose Protected Health Information without authorization by the research participant, the Covered Entity must obtain one of the following from the researcher:

1 An alteration or waiver of Authorization for use or disclosure of information from an IRB or Privacy Board when researchers are unable to use de-identified information and the research could not practicably be conducted if research participant’s authorization is required. See Title 45 CFR 164.512(i)(1)(i). The waiver must:

* Identify the IRB or Privacy Board and the date on which the alteration or waiver of authorization was approved;
* State that the IRB or Privacy Board has determined that the alteration or waiver of authorization, in whole or in part, satisfies the tree criteria in the Rule;
* Contain a brief description of the protected health information for which use or access has been determined to be necessary by the IRB or Privacy Board;
* State that the alteration or waiver of authorization has been reviewed and approved under either normal or expedited review procedures; and
* Be signed by the chair or other member as designated by the chair, of the IRB or the Privacy Board.

Waiver of Authorization approval Criteria. The following criteria should be satisfied for an IRB

or Privacy Board to approval a waiver of authorization under the Privacy Rule:

1. The use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements:
   * An adequate plan to protect the identifiers from improper use and disclosure;
   * 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
   * Adequate written 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 for which the use or disclosure of protected health information 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 protected health information.

1. Review Preparatory to Research. Representation from the researcher, either in writing or orally, that the use or disclosure of the protected health information is solely to prepare a research protocol or for similar purposes preparatory to research, that the researcher will not remove any Protected Health Information from the Covered Entity, and representation that Protected Health Information for which access is sought is necessary for the research purpose. See Title 45 CFR 164.512(i)(1)(ii). This provision might be used, for example, to design a research study or to assess the feasibility of conducting a study.
2. Research on Protected Health Information of Decedents. Representations from the researcher, either in writing or orally, that the use or disclosure being sought is solely for research on the Protected Health Information of decedents, that the Protected Health Information being sought is necessary for the research, and at the request of the covered entity, documentation of the death of the individuals about whom information is being sought. See Title 45 CFR 164.512(i)(1)(iii).
3. Limited Data Sets with a Data Use Agreement. A data use agreement entered into by both the covered Entity and the researcher for research, public health, or health care operations. See Title 45 CFR 164.512(e). a limited data set excludes specified direct identifiers of the individual or of relatives, employers, or household members of the individual. The data use agreement:
4. Establish the permitted uses and disclosures of the limited data set by the recipient,
5. consistent with the purposes of the research, and which may not include any use or disclosure that would violate the Rule if done by the covered entity;
6. Limit who can use or receive the data; and
7. Require that recipient to agree to the following:
   * Not to use or disclose the information other than as permitted by the data use

agreement or as otherwise required by law;

* + Use appropriate safeguards to prevent the use or disclosure of the information other than as provided for in the data use agreement;
  + Report to the covered entity any use or disclosure of the information not provided for by the data use agreement of which the recipient becomes aware;
  + Ensure that any agents, including a subcontractor, to whom the recipient provides the limited data set agrees to the same restrictions and conditions that apply to the recipient with respect to the limited data set; and
  + Not to identify the information or contact the individual.

**C Accounting for Research Disclosures**

The Privacy Rule gives individuals the right to receive an accounting of certain discourse of protected health information made by a Covered Entity. See Title 45 CFR 164.528. This accounting must include disclosures of Protected Health Information that occurred during the six years prior to the individual’s request for an accounting or since April 14, 2003, and must include specified information regarding each disclosure. A more general accounting is permitted for subsequent multiple disclosures to the same person or entity for a single purpose. See Title 45 CFR 164.528(b)(3). Among the types of disclosures that are exempt from this accounting requirement are:

* Research discourses made pursuant to an individual’s authorization,
* Disclosures of the limited data set to researchers with a data use agreement under 45 CFR 164.514(e).

In addition, for disclosures of Protected Health Information for research purposes without the individual’s authorization pursuant to 45 CFR 164.512(i), and that involve at least 50 records, the Privacy Rule allows for a simplified accounting of such disclosures by covered Entities. Under this simplified accounting provision, Covered Entities may proved individuals wit a list of all protocols for which the patient’s Protected Health Information may have been disclosed under 45 CFR 164.512(i), as well as the researcher’s name and contact information. Other requirements related to this simplified accounting provision are found in 45 CFR 164.528(b)(4).

**PROCEDURES**

1. Requests to waive authorization will be reviewed by the IRB. The IRB will follow the requirements of 45 CFR 46 (the Common Rule) and 21 CFR 56 for full or expedited

review. The HIPPA Privacy Rule requires that eight criteria be satisfied in order to grant a waiver of individual Authorization for research uses of PHI.

1. Whenever appropriate, the participants will be provided with additional pertinent information after participation.
2. Researchers will be notified in writing of the IRB’s determination regarding the Waiver of Authorization.