



## Human Research Protection Program Policy

**Policy Number: IV.04**

**Waiver of Authorization (HIPAA) in Human  
Subjects Research**

**Adopted: 11/2005**

**Revised:**

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**AAHRPP DOMAIN I**

### **WAIVER OF AUTHORIZATION (HIPAA) IN HUMAN SUBJECTS RESEARCH**

#### **POLICY**

Researchers whose research is conducted within a Covered Entity under HIPAA (45 CFR 164 section 512) will be knowledgeable about and will comply with the HIPAA policies of their physician practice plans. Generally, researchers whose patients are recruited for a study are required to get HIPAA authorizations from patients to contact them regarding a research study. If the researcher is unable to get Authorization, the UC IRB will review requests to waive authorization for research in accordance with federal standards at 45 CFR 164.512 (i). See [U.S. Department of Health and Human Services](#).

#### **DEFINITIONS**

**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.

**Covered Entity:** (1) A health plan. (2) A health care clearinghouse. (3) A health care provider who transmits any health information in electronic form in connection with a transaction covered by HIPAA. All UC physician practice plans are Covered Entities.

**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.

**Privacy Rule:** Privacy Rule refers to the Standards or 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.



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### PROCEDURES

When reviewing requests to waiver authorization, the IRB will follow the requirements of 45 CFR 46 (the Common Rule) and 21 CFR 56 for full or expedited review. The HIPAA Privacy Rule [45 CFR 164 section 512(l)] requires that eight criteria be satisfied in order to grant a waiver of individual Authorization of research uses of PHI. In addition to these criteria, the federal common Rule (45 CFR 46 section 116(d)) stipulates that “whenever appropriate, the participants will be provided with additional pertinent information after participation.”

The criteria are:

- The research involves no more than minimal risk;
  - Granting of waiver will not adversely affect privacy rights and welfare of the individuals whose records will be used;
  - The project could not practicably be conducted without a waiver;
  - The project could not practicably be conducted without use of PHI;
  - The privacy risks are reasonable relative to the anticipated benefits of research;
  - An adequate plan to protect identifiers from improper use and disclosure is included in the research proposal;
  - An adequate plan to destroy the identifiers at the earliest opportunity, or justification for retaining identifiers, is included in the research proposal;
  - The project plan includes written assurances that PHI will not be re-used or disclosed for other purposes.
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. The IRB will maintain documentation of requests for Waiver of Authorization for 7 years.

#### **Applicable Regulations, Documents:**

45 CFR 164

#### **Other Applicable AAHRPP Domains:**

N/A

**Date Adopted** \_\_\_\_\_ **Signature** \_\_\_\_\_