

IMPLEMENTATION OF HIPAA AND THE PRIVACY RULE
UCR INSTITUTIONAL REVIEW BOARD
April 11, 2003

WHAT IS HIPAA?

HIPAA is the acronym for the Health Insurance Portability and Accountability Act of 1996. The intention of HIPAA is to protect patients from inappropriate disclosures of "Protected Health Information" (PHI) that can cause harm to a person's insurability, employability, etc.

WHAT IS PHI?

PHI is information that can be linked to a particular person and that is created, used, or disclosed in the course of providing a health care service (i.e., diagnosis or treatment).

WHAT IS THE "PRIVACY RULE" AND WHEN MUST WE ENFORCE IT?

The Privacy Rule is a nickname for DHHS' regulation, "Standards for Privacy of Individually Identifiable Health Information," applicable to entities covered by HIPAA. The privacy provisions of HIPAA apply to health information created or maintained by health care providers who engage in certain electronic transactions, health plans, and health care clearinghouses. The DHHS Office for Civil Rights (OCR) is responsible for implementing and enforcing the Privacy Rule, effective April 14, 2003.

WHAT DOES THE PRIVACY RULE HAVE TO DO WITH RESEARCH?

HIPAA affects only that research which uses, creates, or discloses PHI. Researchers have legitimate needs to use, access, and disclose PHI to carry out a wide range of health research studies. The Privacy Rule protects PHI while providing ways for researchers to access and use PHI when necessary to conduct research. In general, there are two types of human research that would involve PHI:

1. Studies involving review of existing medical records as a source of research information. Retrospective studies, such as chart reviews, often do this. Sometimes prospective studies do it also, for example, when they contact a participant's physician to obtain or verify some aspect of the participant's health history.
2. Studies that create new medical information because a health care service is being performed as part of the research, such as testing of a new way of diagnosing a health condition or a new drug or device for treating a health condition. Virtually all sponsored clinical trials that submit data to the U.S. Food and Drug Administration (FDA) will involve PHI.

WHAT IS THE UCR INSTITUTIONAL REVIEW BOARD'S (IRB'S) ROLE?

The IRB will act as a Privacy Board (required by HIPAA) to review the use/disclosure of PHI and to determine whether the subjects should sign an "Authorization" (in addition to the consent to participate in research) or if a Waiver of Authorization (roughly analogous to a Waiver of Consent under the Common Rule) may be granted. The Office of Research Administration will mount an "Authorization" form on the Human Subjects website that researchers can simply download and attach to the informed consent document. Also, all IRB members will have to review a PowerPoint demonstration created by the UC Office of the President, which explains the research consequences of HIPAA. This will be available on UCR's Human Subjects website shortly.

WHAT WILL RESEARCHERS HAVE TO DO DIFFERENTLY?

New Protocols: Researchers will find a new question on the IRB application, "Will this study require the creation, use or disclosure of PHI?" (a definition of PHI will be provided). If they answer "yes," they will need to state whether they will have subjects sign an Authorization form or if they want the IRB to grant a Waiver of Authorization. If the IRB grants a Waiver, it will be noted on the IRB approval letter. Also, if a study involves PHI, all members of the study team will have to complete a HIPAA research tutorial (like the Use of Human Subjects tutorial already on the HS website) before the IRB can review the protocol.

Existing Protocols: Subjects enrolled prior to April 14 are "grandfathered in," meaning their existing consents are HIPAA compliant. New subjects must sign an Authorization unless a waiver of consent has been granted.