HIPAA is Upon Us
Comments by Jeff Mulchahey, IRB Chair
HIPAA Q&A Session April 10, 2003

Although the Privacy Rule is clear in its objectives, specific and meaningful information regarding the procedures necessary to meet those objectives is scarce. This has created considerable uncertainty across the United States as local privacy officials create and implement HIPAA-related procedures. Here are the highlights of how HIPAA will be implemented with regard to human subjects research at UC:

HIPAA Privacy Boards and Authorizations:
The UC IRBs will serve as the Privacy Boards for HIPAA.

The IRB/Privacy Board (IRB) evaluates requests for waivers or alterations of the HIPAA Authorization. The IRB does not review or evaluate authorizations. The various Covered Entities must create their own authorization. There is a HIPAA research authorization available at: http://www.med.uc.edu/irb/HIPAALink.cfm.

Authorizations will be a separate document from the study informed consent document.

Studies Involving Human Subjects:
Individuals who have enrolled in a study (i.e. have signed a consent form) prior to the March 14th HIPAA start date are “grand-fathered in” by the transition provisions of HIPAA. These subjects are not required to sign an authorization except as noted next.

Subjects enrolling on or after April 14th must sign an authorization. Subjects who must be re-consented due to a change in your protocol must sign an authorization. Therefore, anyone who signs a consent on or after April 14th must sign an authorization.

Waivers of authorization are available from the IRB. However, if you can obtain consent, you can obtain an authorization. Don’t ask for a waiver if there is a consent process.

If you are operating a study that involves a telephone screen that collects health information, you need to request a waiver or alteration of authorization for that part of your study. The main part of the study will still require an authorization.

If you are operating a study with a waiver of consent, you need to request a waiver of authorization from the IRB.

The waiver request form is available at: http://www.med.uc.edu/irb/HIPAALink.cfm. Complete the form on the form; you may use additional pages if necessary. Do not provide or refer to an attachment. The waiver form is your ticket; the attachment can and will get separated from the waiver form.
If you are operating a study judged to be exempt from IRB oversight, you are not covered by HIPAA.

**Identification of Potential Research Participants:**
HIPAA allows the review information within a Covered Entity. Records obtained from a patient within your practice corporation can be reviewed by individuals within that practice corporation (i.e. the Covered Entity). This means you can review charts to evaluate your patients for participation in your clinical studies.

You cannot review charts outside your Covered Entity without either an authorization from the individual or a waiver of authorization. You will probably be unable to get authorization because you do not know *a priori* whom to ask, so a waiver will be required.

Waivers must be specific as to their use 1: Do not ask for a waiver to review every chart in the hospital to evaluate all those patients for eligibility in every clinical study you run. Broad requests such as this will be denied.

Waivers must be specific as to their use 2: Each waiver you request must be as a separate study-specific waiver request. If you have 20 open studies and you need a waiver to recruit for those 20, then you need 20 separate waiver requests.

The “activities preparatory to research” provisions of the Privacy Rule may eliminate the need for a waiver, depending the relationships of the entities and the information involved.

The relationships of the various affiliated corporations to one another and to the University are complicated. If you have questions concerning those relationships as they relate to the various Covered Entities, ask your organization’s Privacy Director.

**Disclaimer:**
HIPAA is a new adventure for all of us. The research community will gain additional knowledge as time passes and our experience with HIPAA grows. Our interpretation and implementation of HIPAA is likely to change with this added knowledge. Watch the IRB and HIPAA websites for new information as this adventure continues.