

## **Impact of HIPAA Medical Privacy Rule on Research at USC**

The Health Insurance Portability and Accountability Act (HIPAA) of 1996 included standards for the protection of individually identifiable personal health information (PHI). To implement these privacy protections, the Department of Health and Human Services (HHS) issued a final Privacy Rule effective on April 14, 2003. The Rule governs how health care providers use and disclose their patients PHI, including use and disclosure for research purposes. While USC faculty members are not directly subject to the Rule, university researchers across the country will be affected if their research protocols require the use of PHI. (Note: The USC School of Medicine Specialty Clinics is a HIPAA "covered entity" and has taken the necessary steps to become HIPAA compliant.)

USC faculty members conduct a variety of research projects that require access to (PHI). They obtain the PHI from our affiliated hospitals, public and private health care clinics, and physicians' private practices. Each of these covered entities (CE) must have procedures in place to ensure HIPAA compliance. It is likely that there will be differences in how each CE interprets the HIPAA requirements. It is even possible that some health care providers will withdraw from participation in research rather than deal with the increased regulatory requirements. However, it is possible to conduct research reasonably and still comply with the Rule. In cases where researchers encounter difficulties in working with covered entities, The Office of Research Compliance (ORC) will be available to offer guidance and mediation.

HIPAA requires written authorization from the patient before disclosure of his/her PHI. In most cases, the researcher will have to rely on the CE to obtain patient authorization. The authorization mechanism will vary among CEs, potentially complicating the subject recruitment process. In addition, it will be important for clinical researchers (physicians) to be mindful of their dual role and not use information gained during treatment for research purposes without appropriate authorization.

Before the Privacy Rule, protection of human subjects in research focused primarily on assuring that research projects were performed ethically and that subject participation was based on informed consent. It is the duty of the Institutional Review Board (IRB) to ensure that research involving human subjects is ethical and legal (Common Rule and FDA regulation). The Privacy Rule supplements the current human subject regulations. While the Privacy Rule requires authorization for use and disclosure of PHI, it allows for a waiver of authorization in some limited circumstances. An IRB or a Privacy Board in accordance with specific requirements can grant the waiver. The CE may use its own IRB/Privacy Board or accept a waiver approved by another IRB. This provision, when used appropriately, could mitigate many of the recruitment difficulties brought about by the authorization requirement.

The USC IRB will assume the role of USC's Privacy Board.

To summarize, the USC research community will feel the impact of HIPAA when collaborating with health care providers, recruiting subjects through "covered entities", accessing medical records, and through increased responsibilities for the IRB. Questions related to HIPAA should be referred to the Office of Research Compliance (ORC) at 777-7095.