



UNIVERSITY OF FLORIDA

Institutional Review Board
Health Science Center
<http://irb.ufl.edu/>

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To: All Faculty and Staff Conducting Research on Human Subjects

On April 14, 2003, all human research conducted at or by the University of Florida, Shands Hospitals, the Malcom Randall VA Hospital, and all other similar organizations throughout the country must be in compliance with the new Health Insurance Portability and Accountability Act (HIPAA) Privacy regulations. The regulations contain stringent new requirements that govern the privacy and confidentiality of research subjects' health information. As you are probably already aware HIPAA violations carry the possibility of personal criminal fines and imprisonment, therefore it is in your best interest for you and all of your research staff to make sure that you get proper training.

To ensure that UF's researchers are able to carry on their research without incurring legal liability for themselves and for UF, all principal investigators will be **required** to attend a one-hour HIPAA research training session before April 14, 2003. The times and dates for these training sessions are available at the following link: <http://irb.ufl.edu/irb01/HIPAA.htm>. Further, in preparation for HIPAA:

- Please review your current active protocols and close (by submitting appropriate documentation for closure to the IRB) any of those protocols that are not currently active. This will save you and the IRB additional work.
- Current active protocols on which you will continue to enter subjects after April 14, 2003 will require you to submit a revised informed consent or an addendum to the consent; templates for both will be provided by the IRB. These revisions must be approved by the IRB before that date (thus you must submit before April 14, 2003). HIPAA may also require other changes, in particular, how you recruit subjects. Those changes must be submitted and approved by the IRB. (Note: subjects that have consented prior to April 14, 2003, will not need to be re-consented).
- In order to avoid personal legal liability you will need to make the HIPAA-required changes to your active protocols before April 14, 2003. If these changes are not made to your protocols they will be closed to further subject accrual until such changes are reviewed and approved by the IRB.

This process will require a time investment by each investigator, and a significant time investment by the IRB and the IRB Office Staff. Please go early to the **mandatory** HIPAA training session to give yourself time to make these changes and avoid any interruption in your research.

Sincerely,

Winifred Phillips, D.Sc.
Vice President
Office of Res Tech & Grad Educ

R. Peter Iafrate, Pharm.D.
Chairman
Health Science Center IRB