# PROCEDURES FOR HIPAA COMPLIANCE
# FOR ACTIVE STUDIES

**Please read this carefully. It includes new information and procedures as of March 25, 2003.**

The following applies to each active study where as part of the research, you or anyone who assists you:

(i) accesses or obtains information from patient medical or billing records maintained by the University of Miami or Jackson Health Systems ***or***

(ii) creates information that may be used to provide a research subject with medical care/treatment at the University of Miami or Jackson Health Systems

[**NOTE:** For purposes of item (ii), "creating health information" consists of collecting or creating information that will be used in diagnosing a condition and/or providing treatment as part of the research study. Collecting a medical history from the study participant without placing the information in or accessing their medical records is not generally considered "creating health information". Conducting tests or evaluations not meant to be used for diagnosis or treatment, but rather, for study screening or research information/background purposes]

It is suggested that you provide the necessary information/forms to the Human Subjects Research Office (HSRO) as soon as reasonably possible to avoid any delays in processing and approval. Studies that require HIPAA Authorization or waiver of Authorization for activities to be conducted on or after April 14, 2003 cannot proceed without the approvals required below.

## 1. Studies approved with Informed Consent prior to April 14, 2003:

- No further action is required and the study can continue according to the approved protocol as long as no new participants will be accrued and no need arises for study participants to be re-consented (i.e. no amendments or changes are made to the study/protocol that require enrolled participants to be re-consented) on or after April 14, 2003

- If a study will accrue new participants on or after April 14, 2003, and no need arises for those study participants already consented prior to April 14, 2003 to be re-consented, the Investigator can rely on the consent form already executed prior to April 14, 2003 for the existing study participants and does not have to obtain HIPAA authorization from those

participants. Keep in mind, however, that as described in the next bullet point, new accruals to the study on or after April 14, 2003 will need to receive both informed consent and HIPAA authorization.

- If on or after April 14, 2003 new subjects will be accrued, accrual is reopened or an amendment or change to the protocol requires that participants already consented be re-consented, participants newly accrued or to be re-consented must receive a HIPAA Authorization (Form B) along with the new or revised Informed Consent. In these cases, a HIPAA Authorization for the study must be submitted to the HSRO for administrative review prior to enrolling new participants or re-consenting existing participants.

**2. Studies approved with waiver of Informed Consent prior to April 14, 2003:**

- No further action is required and the study can continue according to the approved protocol as long as ***no changes*** to the approved protocol for which the waiver of consent was granted are made on or after April 14, 2003.

- If changes are proposed or required to the approved protocol on or after April 14, 2003, the Research Protocol Application – HIPAA Addendum (Form A) and a Request for Waiver of Authorization (Form F) for the study must be submitted with the protocol Amendment to the HSRO for review and approval of the IRB.

If you have any questions please contact the Human Subjects Research Office at (305) 243-3195 for further assistance.