DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

FOR US POSTAL SERVICE DELIVERY:
Office for Human Research Protections
6100 Executive Boulevard, Suite 3B01
National Institutes of Health (MSC 7507)
Rockville, Maryland 20892-7507

FOR HAND DELIVERY OR EXPRESS MAIL:
Office for Human Research Protections
6100 Executive Boulevard, Suite 3B01
Rockville, Maryland 20852

Telephone: 301-435-5654
FAX: 301-402-0527
E-mail: sandy_leikin@nih.gov

January 17, 2001

Dr. Dorothea Wilson
Vice President for Research
University of Texas Medical Branch at Galveston
Suite 6.606 Administration Building
301 University Blvd.
Galveston, TX 77555-0130

RE: Human Research Subject Protections Under the Multiple Project Assurance (MPA) M-1172

Dear Dr. Wilson:

The Office for Human Research Protections (OHRP) has reviewed your December 14, 2000 quarterly progress report, the revised Institutional Review Board (IRB) Forms, IRB Policies and Procedure Manuals, and the minutes of recent IRB meetings.

Based on its review, OHRP finds that the University of Texas Medical Branch at Galveston (UTMB) has greatly enhanced its system for protection of human subjects. Among the enhancements noted by OHRP are the following:

(1) The UTMB has implemented a multifaceted education program to ensure that all IRB members, all IRB staff, and all research investigators are educated on an ongoing basis about the ethical principles and regulatory requirements for the protection of human subjects.

(2) The UTMB has expanded the number of IRB's from one to two, resulting in a significant reduction in the volume of research protocols reviewed and overseen by each IRB. Furthermore, UTMB has restructured the UTMB Office of the IRB's and increased its staff at nearly all levels.

(3) The UTMB has revised it written IRB policies and procedures in response to OHRP's prior guidance. In particular, the UTMB policy and procedures have been revised to ensure that the determinations required for approval of research under HHS regulations at 45 CFR 46.111 and Subparts B, C and D will be made.

(4) The minutes of recent IRB meetings clearly document substantive and meaningful initial and continuing review of human subject research.

Furthermore, OHRP finds that the UTMB has adequately completed all required actions stipulated by OHRP in its September 14, 2000 letter.

As a result of the above findings, effective immediately, OHRP has removed the restriction on the UTMB Multiple Project Assurance (M-1172) and is closing its compliance oversight investigation of this matter.

OHRP appreciates the continued commitment of your institution to the protection of human subjects. Please do not hesitate to contact me should you have any questions.

Sincerely,

Sanford Leikin, M.D.
Compliance Oversight Coordinator
Division of Compliance Oversight

cc Dr. Greg Koski, OHRP
Dr. Melody Lin, OHRP
Dr. Michael Carome, OHRP
Dr. Katherine Duncan, OHRP
Mr. Barry Bowman, OHRP
Ms. Elyse Summers, OHRP
Dr. Jeff Cohen, OHRP
Ms. Inese Beitins, OHRP
Commissioner, FDA
Dr. David Lepay, FDA
Dr. James F. McCormack, FDA
Dr. John D. Stobo, President, UTMB
Dr. Wayne Patterson, IRB Director, UTMB
Dr. Frank C. Schmalstieg, Chair, IRB #1, UTMB
Dr. Joseph B. Zwischenberger, Chair, IRB #2, UTMB