DEPARTMENT OF HEALTH & HUMAN SERVICES

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September 26, 2000

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 Ms. Wilson:

The Office for Human Research Protections (OHRP) has reviewed your September 20, 2000 letter responding to the required actions stipulated in OHRP's letter of September 14, 2000.

Regarding **Action 1** required by OHRP in its September 14, 2000 letter, OHRP finds that the University of Texas Medical Branch (UTMB) has developed satisfactory corrective action plans that address each OHRP-cited deficiency and concern. In particular, OHRP acknowledges that UTMB plans to establish a second Institutional Review Board (IRB) under its MPA.

Regarding **Actions 2, 3, and 6** required by OHRP in its September 14, 2000 letter, OHRP acknowledges your report that relevant Federally supported research projects were suspended by UTMB as required by OHRP. Furthermore, regarding **Action 6** required by OHRP, please note that resumption of enrollment of prisoner subjects in research supported by the Department of Health and Human Services (HHS) may not resume until the following conditions have been satisfied:

(1) UTMB has submitted written certification to OHRP that the IRB has made the findings required by HHS regulations at 45 CFR 46.305(a).

(2) OHRP, acting on behalf of the Secretary of HHS, has judged the research to involve solely one of the four categories of research permissible under HHS regulations at 45 CFR 46.306(a)(2).

(3) OHRP has provided written confirmation to UTMB that (a) UTMB's certification has been reviewed; and (b) OHRP has determined that the research involves solely one of the four categories of research permissible under HHS regulations at 45 CFR 46.306(a)(2).

OHRP acknowledges UTMB's plan to implement **Actions 7 to 10** recommended by OHRP in its September 14, 2000 letter.

Additional OHRP Guidance

Regarding UTMB IRB Form # 2C, OHRP provides the following additional guidance:

(1) Item 6 on page 2 asks the investigator to respond to the following questions:

(a) "When the research requires follow-up beyond the period of incarceration, have provisions for locating the individual?"

(b) "Are participants informed of how follow-up will take place if such is required?"

OHRP finds that responses to these questions would fail to provide the IRB with sufficient information to make the finding required by HHS regulations at 45 CFR 46.305(a)(7)(i.e., where the IRB finds there may be a need for follow-up examination or care of participants after the end of their participation, adequate provisions have been made for such examinations or care, taking into account the varying lengths of individual prisoners' sentences and for informing participants of this fact). It would appear to be appropriate to ask investigators to describe (i) the potential complications that may result from participation in the research; (ii) the possible duration of such complications; (iii) the type of examinations and care that would typically be needed for such complications; and (iv) and the provisions for such examinations and care to subjects after their participation in the research has ended.

(2) The last sentence on page 3 states the following:

"OHRP concurrence if research is covered under 46.306(a)(2)(C) or requires the assignment of prisoners that may not benefit from the research (46.206(a)(2)(D))."

Please note that OHRP must receive appropriate certification for all HHS-supported research involving prisoners as subjects and must concur that the research involves solely one of the four categories of research permissible under HHS regulations at 45 CFR 46.306(a)(2). For HHS-supported research the requirement for OHRP concurrence should not be limited to research activities permissible under HHS regulations at 45 CFR 46.306(a)(2)(C) and (D).

Pending Required Actions

Regarding **Action 4** required by OHRP in its September 14, 2000 letter, OHRP looks forward to receiving by September 28, 2000, UTMB's complete list of all suspended research protocols, including project title, IRB number, applicable Federal award number, and principal investigator name.

Regarding **Action 5** required by OHRP in its September 14, 2000 letter, OHRP looks forward to receiving UTMB's first quarterly progress report by December 15, 2000. Please include the following with this report:

(1) An update on UTMB's progress in implementing its corrective action plans and its educational programs for all IRB members, all IRB staff, and all research investigators about the ethical principles and regulatory requirements for the protection of human subjects. Please

describe specific education programs that have been completed by, or planned for, each of these groups of individuals.

(2) A status report on the IRBs re-review of Federally supported research projects that were suspended in response to OHRP's September 14, 2000 letter.

(3) A status report on research project for which enrollment of prisoners was suspended in response to OHRP's July 10, 2000 letter.

(4) The minutes all IRB meetings convened since September 14, 2000.

(5) Any revised written IRB policies and procedures

(6) An update on IRB resources and staff support.

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

Sincerely,

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

cc: Dr. John D. Stobo, President, UTMB
Dr. George M. Bernier, Jr., Vice President for Education, UTMB
Dr. Wayne Patterson, IRB Director, UTMB
Dr. Frank C. Schmalstieg, Chairperson, IRB, UTMB
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