DEPARTMENT OF HEALTH & HUMAN SERVICES

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Office of Public Health and Science

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August 28, 2000

Mr. Robert Colvin
President and Chief Executive Officer
Memorial Health University Medical Center
P. O. Box 23089
Savannah, Georgia 31403

Richard Leighton, M.D.
Chair, Institutional Review Board (IRB)
Memorial Health University Medical Center
P. O. Box 23089
Savannah, Georgia 31403

RE: Human Subjects Protections Under Cooperative Project Assurance (CPA) # T-4262

Dear Mr. Colvin and Dr. Leighton:

The Office for Human Research Protections (OHRP), formerly the Office for Protection from Research Risks (OPRR), has reviewed the July 12, 2000 Memorial Health University Medical Center (MHUMC) report and the revised Institutional Review Board (IRB) policies and procedures

Based on its review, OHRP makes the following determinations:

(1) OHRP finds that MHUMC has developed satisfactory corrective action plans to address the deficiencies and concerns cited in OHRP's June 19, 2000 letter.

(2) OHRP finds that the MMC has revised and expanded its written IRB policies and procedures. However, the IRB policies and procedures should be further expanded to include additional operational details for the following procedures:

(a) The procedure the IRB will follow for conducting continuing review of research (e.g., what documents does the primary reviewer receive and review, and what documents do other IRB members receive and review).

(b) The procedure for ensuring prompt reporting to appropriate institutional officials, and Department or Agency head and OHRP of (i) any unanticipated problems involving risks to subjects or others, (ii) or any serious or continuing noncompliance.

(3) OHRP acknowledges the list of suspended Department of Health and Human Services (HHS) supported research projects involving human subjects that failed to undergo substantive and meaningful continuing review subsequent to June 20, 1999.

(4) OHRP acknowledges receipt of the up-dated IRB membership rosters for the General IRB and the Oncology IRB. In reviewing these rosters, OHRP notes that Ms. Mary Ann Beil is both an IRB member and the signatory official on the MHUMC CPA. Because of the potential conflicts of interest that may result from the same individual being both the signatory official on an Assurance and an IRB member, either a revised CPA with a new signatory official, or revised IRB membership rosters deleting Ms. Beil as a member should be submitted to OHRP's Assurance Branch.

In view of the above determinations and assuming MHUMC (i) further modifies its written IRB policies and procedures as noted above, (ii) modifies its CPA or IRB membership rosters as noted above, and (iii) ensures IRB review of any HHS-supported research that remains suspended, there should be no need for further involvement of OHRP's Compliance Oversight Branch in this matter.

OPRR 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,

Sanford Leikin, M.D.
Compliance Oversight Coordinator
Division of Human Subject Protections

cc: Dr. Melody Lin, OHRP
Dr. Michael Carome, OHRP
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Dr. David Lepay, FDA
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