DEPARTMENT OF HEALTH & HUMAN SERVICES

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July 12, 2001

John Mendelsohn, M.D.
President
The University of Texas M.D. Anderson Cancer Center
1515 Holcombe Boulevard
Houston, TX 77030

RE: Human Research Subject Protections Under Multiple Project Assurance (MPA) M-1098

Research Project A: Phase II Study of Allogeneic/Syngeneic Blood Stem Cell Transplantation in Patients with High Risk Lymphoma (DM 95-182)

Research Project B: Compassionate Use of AmBisome for the Treatment of Invasive Fungal Infections in Patients Intolerant to or with Disease Unresponsive to Standard Antifungal Therapy (DM 96-274)

Dear Dr. Mendelsohn:

The Office for Human Research Protection (OHRP) has reviewed your June 8, 2001 report. Based upon review of your report, OHRP notes the following:

(1) University of Texas M.D. Anderson Cancer Center (MD Anderson) has clarified its process for the review of research. This process includes a two tiered system in which scientific issues are addressed in one tier and human subjects issues are addressed in the second tier. This system is applied to both initial and continuing reviews.

(2) MD Anderson has adequately described its new Institutional Review Board (IRB) which will be utilized primarily for continuing review of research.

(3) MD Anderson has incorporated the use of a scribe in its IRB meetings and has improved the content of its IRB minutes to provide greater documentation of issues discussed and their outcomes.

OHRP has determined that MD Anderson has adequately addressed the questions and concerns raised in OHRP's letter of May 31, 2001.

As a result of the above determination, OHRP anticipates no further involvement in the above matter. Of course, OHRP must be notified should new information be identified which might alter this determination.

At this time, OHRP would like to provide the following additional guidance:

(1) Department of Health and Human Services regulations at 45 CFR 46.115(a)(2) require that minutes of IRB meetings be in sufficient detail to show attendance at the meeting. OHRP recommends that in order to document a quorum at an IRB meeting, minutes of such meetings should include a listing of those members present and absent. Additionally, in order to document the continued existence of a quorum, OHRP recommends that votes be recorded in the minutes using the following format: Total = 15; Vote: For-14, Opposed-0, Abstained-1 (NAME).

(2) Where HHS regulations require specific findings on the part of the IRB, such as (a) approving a procedure which alters or waives the requirements for informed consent [see 45 CFR 46.116(d)]; (b) approving a procedure which waives the requirement for obtaining a signed consent form [see 45 CFR 46.117(c)]; (c) approving research involving prisoners (see 45 CFR 46.305-306); or (d) approving research involving children (see 45 CFR 46.404-407), the IRB should document such findings. OHRP strongly recommends that all required findings be fully documented in the IRB minutes, including protocol-specific information justifying each IRB finding.

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

Sincerely,

Patrick J. McNeilly, Ph.D.
Compliance Oversight Coordinator
Division of Compliance Oversight

cc: Mr. R. Dan Fonatine, Chief Legal Officer, M.D. Anderson Cancer Center
Dr. Aman Budzar, IRB Chairperson, M.D. Anderson Cancer Center
Dr. Leonard Zwelling, M.D. Anderson Cancer Center
Dr. Carleen Brunelli, M.D. Anderson Cancer Center
Commissioner, FDA
Dr. David Lepay, FDA
Dr. James McCormack, FDA

Dr. Greg Koski, OHRP
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Mr. Barry Bowman,OHRP