



**FOR US POSTAL SERVICE DELIVERY:**

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July 7, 2000

Joseph J. Ferretti, Ph.D.  
Senior Vice President and Provost  
University of Oklahoma Health Sciences Center  
Robert M. Bird Library Building, Room 221  
1000 Stanton L. Young Boulevard  
Oklahoma City, Oklahoma 73104

Nancy L. Nisbett  
Director, Research Administration  
University of Oklahoma Health Sciences Center  
P.O. Box 26901  
Robert M. Bird Library Building, Room 121  
1000 Stanton L. Young Boulevard  
Oklahoma City, Oklahoma 73190

**RE: Human Research Subject Protections Under Multiple Project Assurance  
(MPA) M-1448**

**Research Project: Allogeneic Melanoma Cell Line (IIB-MEL-J, University of Oklahoma)  
Vaccine**

**IRB Project Number: # 96-0080-T**

**Principal Investigator: Dr. Michael McGee**

Dear Dr. Ferretti and Ms. Nisbett:

The Office for Human Research Protections (OHRP) has reviewed your July 7, 2000 letter responding to OHRP's June 29, 2000 letter concerning the above referenced research and the system for protecting human subjects at the University of Oklahoma Health Sciences Center, Tulsa (UOHSC-Tulsa).

**OHRP Findings**

(1) OHRP finds that the UOHSC-Oklahoma City IRB has developed an appropriate plan for contacting all surviving subjects who participated in the melanoma vaccine research, as well as the closest identified relative(s) of deceased subjects, and informing them of the previously undisclosed events that lead to the termination of the research and the potential risks associated with these events. OHRP encourages the UOHSC to proceed with implementation of this plan expeditiously.

(2) OHRP finds that the UOHSC has developed an appropriate plan for notifying participating investigators at remote study sites involved in the conduct of the melanoma vaccine research of the previously undisclosed events that lead to the termination of the research, including the findings cited in the March 16, 2000 GCP and GMP Audit Reports, and the potential risks associated with these events.

(3) OHRP acknowledges your report that 26 Federally supported projects being conducted by the UOHSC-Tulsa have been suspended, as well as all other research involving human subjects.

(4) OHRP acknowledges that (i) Dr. Daniel Plunket has been removed as Chair of the UOHSC-Tulsa IRB, and (ii) the UOHSC-Tulsa IRB has been disbanded.

OHRP looks forward to receiving your revised MPA and corrective actions plans requested by OHRP in its June 29, 2000 letter.

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

Sincerely,



Michael A. Carome, M.D.  
Chief, Compliance Oversight Branch  
Division of Human Subject Protections

cc: Ms. Elizabeth H. Cothran, Research Project Coordinator, IRB, UOHSC  
Ms. Julie H. Hall, Sponsored Programs Administrator, UOHSC-Tulsa  
Dr. Harold L. Brooks, Dean, UOHSC-Tulsa  
Dr. Joan Walker, Chair, IRB-01, UOHSC  
Dr. Daniel C. Plunket, UOHSC-Tulsa  
Dr. Michael McGee, Surgery Department, UOHSC-Tulsa  
Dr. Thomas Broughan, Chairman, Department of Surgery, UOHSC-Tulsa  
Dr. John Mather, Department of Veterans Affairs  
Commissioner, FDA  
Dr. David Lepay, FDA  
Dr. James F. McCormack, FDA  
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