DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

Office for Human Research Protections
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August 16, 2006

Myron Rosenthal, Ph.D.
Senior Associate Dean and Director, Human Subjects Research Office
Faculty/Professional Affairs
University of Miami
Park Plaza East, Suite M
Miami, FL 33136

RE: Human Research Subject Protections Under Federalwide Assurance FWA-2247

Research Project: A 4-Year, Double Blind, Randomized, Placebo-Controlled Study of Atorvastatin as Preventative of CHD End Points in Patients with (Type II) Noninsulin-Dependent Diabetes Mellitus
Principal Investigator: Dr. Ronald Goldberg
Project Number: 981-71-27

Dear Dr. Rosenthal:

The Office for Human Research Protections (OHRP) has reviewed the University of Miami's (UM) July 23, 2006 report responding to determinations of noncompliance with Department of Health and Human Services (HHS) regulations for the protection of human research subjects (45 CFR part 46).

In its August 9, 2005 letter, OHRP made the following determination, among others:

HHS regulations at 45 CFR 46.109(e) require that continuing review of research be conducted by the institutional review board (IRB) at intervals appropriate to the degree of risk, and not less than once per year. OHRP found that the UM IRB failed to conduct continuing review of research at least once per year for numerous studies. In assessing UM's corrective action to address this finding, OHRP requested an update on the status of the UM IRBs and whether they are convening meetings; and, if not, when you expect them to begin convening meetings. OHRP acknowledges that the two internal IRBs currently designated under the UM FWA have been reviewing protocols since February of 2006. While UM continues to out-source the review of many studies to an independent IRB, UM is currently recruiting individuals to serve on a third UM IRB.

OHRP finds the corrective actions taken to be adequate and appropriate under the UM FWA. As a result there should be no need for further involvement of OHRP in this matter. Of course, OHRP must be notified should new information be identified which might alter these determinations. However, please note that OHRP plans to conduct an on-site evaluation of UM's system for the protection of human subjects within the next 12 months.

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

Sincerely,

Kristina C. Borror, Ph.D.
Director
Division of Compliance Oversight

cc: Dr. Steven Ullman, Vice Provost for Faculty Affairs, UM
Dr. Leo Twiggs, Assistant Vice Provost, Human Subjects Research Office, UM
Ms. Kelly Insignares, Exec Dir for HSRO, UM
Ms. Judith Aguirre, Dir for Regul Affairs and Educ Initiatives, UM
Dr. Thomas Sick, chair, UM IRB #1
Dr. Stephen Sapp, IRB chair, UM Social and Behavioral Sci Committee
Ronald A. Gadde, chair, Western Institutional Review Board-IRB/Panels 1-8 & 11-12
Commissioner, FDA
Dr. David Lepay, FDA
Dr. Sam Shekar, NIH
Dr. Bernard Schwetz, OHRP
Dr. Melody H. Lin, OHRP
Dr. Michael Carome, OHRP
Ms. Shirley Hicks, OHRP
Dr. Irene Stith-Coleman, OHRP
Ms. Carla Brown, OHRP
Ms. Patricia El-Hinnawy