**DEPARTMENT OF HEALTH & HUMAN SERVICES**

**Office of the Secretary**
**Office of Public Health and Science**

**Office for Human Research Protections**
**The Tower Building**
**1101 Wootton Parkway, Suite 200**
**Rockville, Maryland 20852**

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September 14, 2007

Myron Rosenthal, Ph.D.
Vice Provost for Human Subject Research
University of Miami
1500 N.W. 12th Avenue, Suite 1002
Miami, FL 33136

**RE: Human Research Subject Protections Under Federalwide Assurance (FWA)2247**

**Research Project: Research involving the collection and analysis of data on the use of intravitreal Avastin for treatment of patients with age-related macular degeneration and other retinal diseases**
**Principal Investigators: Phillip Rosenfeld, M.D.**

Dear Dr. Rosenthal:

The Office for Human Research Protections (OHRP) has reviewed the University of Miami's (UM) August 28, 2007 response to OHRP's July 18, 2007 letter that requested UM's revised IRB written procedures for the following, as required by HHS regulations at 45 CFR 46.103(a) and 46.103(b)(4) and (5):

(a) The procedures which the IRB will follow for determining which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review.

(b) The procedures for ensuring prompt reporting to appropriate institutional officials, any department or agency head, and OHRP of: (a) any unanticipated problems involving risks to subjects or others; (b) any serious or continuing noncompliance with 45 CFR part 46 or the requirements or determinations of the IRB; and (c) any suspension or termination of IRB approval.

Based upon its review, OHRP finds that the policies and procedures described in the UM response adequately address OHRP's July 18, 2007 request and are 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 this determination.

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,

Paul J. Andreason, MD
Compliance Oversight Coordinator
Division of Compliance Oversight

cc: Dr. Thomas Sick, Chair, UM IRB #1
Dr. Ofelia Alvarez, Chair, UM IRB #2
Dr. Charles S. Carver, IRB Chair, UM Social and Behavioral Science Committee
Ms. Kelly Insignares, Exec Dir for HSRO, UM
Dr. Carmen Puliafito, UM
Dr. Phillip Rosenfeld, UM
Commissioner, FDA
RADM Linda Tollefson, FDA
Dr. Bernard Schwetz, OHRP
Dr. Melody H. Lin, OHRP
Dr. Michael Carome, OHRP
Dr. Kristina Borror, OHRP
Ms. Shirley Hicks, OHRP
Dr. Irene Stith-Coleman, OHRP
Ms. Patricia El-Hinnawy, OHRP
Dr Kevin Prohaska, OHRP
Ms. Kelley Booher, OHRP
Mr. Barry Bowman, OHRP