DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

Office for Human Research Protections
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December 21, 2001

Thomas Q. Morris, M.D.
Vice President for Health Sciences
Columbia University Health Sciences Division
630 West 168th Street
Room 2-401
Mail Box No. 27
New York, New York 10032

RE: Human Research Subject Protections Under Multiple Project Assurance (MPA) M-1356

Research Project: Does Prayer Influence the Success of In Vitro Fertilization-Embryo Transfer? *Journal of Reproductive Medicine*. 2001, 46(9):781-787
Investigators: Kwang Y. Cha, M.D., Daniel P. Wirth, J.D., M.S., and Rogerio A. Lobo, M.D.

Dear Dr. Morris:

The Office for Human Research Protections (OHRP) has reviewed your November 28, 2001 report regarding indications of possible noncompliance with Department of Health and Human Services (HHS) regulations for the protection of human subjects involving the above-referenced research.

OHRP acknowledges the following findings and corrective action presented in your report:

(1) Columbia University, Health Sciences (CUHS) acknowledged noncompliance with its MPA and its own policies and procedures. In specific, Dr. Lobo, a professor at CUHS, never presented the above research to the Columbia Presbyterian Medical Center (CPMC) Institutional Review Board (IRB).

(2) The study (a) was initiated in Korea by non-CUHS investigators; (b) was reviewed and

approved by an "internal review board" in Korea; (c) involved patients seen at the Cha General Hospital, Seoul, Korea between December 1998 and March 1999; and (d) was not supported by HHS or any other U.S. Federal Department or Agency.
(3) Dr. Lobo first learned of the study from Dr. Cha 6-12 months after the study was completed. Dr. Lobo primarily provided editorial review and assistance with publication.
(4) The CPMC IRB Office will perform an educational in-service for Dr. Lobo's department.

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,

Michael A. Carome, M.D.
Director
Division of Compliance Oversight

cc: Dr. Andrew Wit, Chair, CPMC IRB
Mr. Paul Papagni, J.D., Administrative Director, CPMC IRB
Dr. Rogerio Lobo, CUHS
Commissioner, FDA
Dr. David Lepay, FDA
Dr. James F. McCormack, FDA
Dr. Greg Koski, OHRP
Dr. Melody H. Lin, OHRP
Dr. Jeffrey Cohen, OHRP
Mr. George Gasparis, OHRP
Ms. Yvonne Higgins, OHRP
Mr. Barry Bowman, OHRP