



Office for Human Research Protections
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April 23, 2002

James Wagner
Interim President
Case Western Reserve University
10900 Euclid Avenue
Cleveland, OH 44106-7004

Farah M. Walters
President and CEO
University Hospitals of Cleveland
11100 Euclid Avenue
Cleveland, OH 44106-5001

RE: Human Research Subject Protections Under Multiple Project Assurance (MPA) M-1521

Research Project: A Multicenter, Double-Blind, Placebo-Controlled Study of Estrogen Replacement Therapy in Patients with Mild to Moderate Alzheimer's Disease

Research Publication: Estrogen Replacement Therapy for Treatment of Mild to Moderate Alzheimer Disease: A Randomized Controlled Trial, Mulnard, et al. JAMA 2000; 283: 1007-15.

Principal Investigator: Elisabeth Koss, Ph.D.

Protocol Number: 07-95-46

Dear Mr. Wagner and Ms. Walters:

The Office for Human Research Protections (OHRP) has reviewed the Case Western Reserve University's (CWRU) and University Hospitals of Cleveland's (UHC) report dated April 22, 2002, that was submitted in response to OHRP's March 26, 2002 letter to CWRU regarding the above-referenced research. Based upon its review, OHRP has determined that the corrective actions taken by the institutions appropriately address the issues raised.

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,

Kristina C. Borrer, Ph.D.
Compliance Oversight Coordinator
Division of Compliance Oversight

cc: Ms. Christian LaMantia, CWRU
Mr. Terry R. White, MetroHealth System
Mr. William D. Montague, Louis Stokes Dept of VA Medical Center
Dr. William Dahms, IRB Chair, UHC
Mr. Philip A. Cola, UHC
Dr. Elisabeth Koss, CWRU
Dr. John Mather, ORCA, VA
Commissioner, FDA
Dr. David Lepay, FDA
Dr. Greg Koski, OHRP
Dr. Michael A. Carome, OHRP
Dr. Melody H. Lin, OHRP
Mr. George Gasparis, OHRP
Dr. Harold Blatt, OHRP
Mr. Barry Bowman, OHRP