DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

Office for Human Research Protections
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John L. Anderson, Ph.D.
Provost and University Vice-President
Case Western Reserve University
Adelbert Hall Second Floor
10900 Euclid Avenue
Cleveland, OH 44106-7001

RE: Human Research Subject Protections Under Federalwide Assurances (FWA)-5367 and FWA-4428

Dear Drs. Hahn and Anderson:

The Office for Human Research Protections (OHRP) has reviewed your submission dated May 24, 2006 in response to OHRP's March 2, 2006 letter responding to allegations of non-compliance with Department of Health and Human Services (HHS) regulations for the protection of human research subjects (45 CFR Part 46). OHRP has determined that the allegations of non-compliance with 45 CFR 46 summarized below can not be substantiated:

> The allegation involved the failure to obtain legally effective informed consent of the subject as required by HHS regulations at 45 CFR 46.116. In specific it was alleged that the subject was enrolled without her consent in a study on the treatment of Alzheimer's disease, was subjected to a venipuncture to retrieve samples for Apo E testing and was treated with a drug of the statin class for Alzheimer's disease. OHRP's review could not substantiate either of these allegations. OHRP found that the Apo E testing was part of a battery of laboratory assays that were accepted as clinical practice to assess the risk of cardiovascular disease. Some of the subject's clinical laboratory test results were included in a Cleveland Clinic Foundation Institutional Review Board (CCF IRB)

approved registry of clinically indicated laboratory tests. The CCF IRB had waived the requirement for informed consent for this registry. The subject's Apo E testing was not part of this registry. There was likewise no evidence that the subject was enrolled in a research study on the use of any drug in the treatment of Alzheimer's disease.

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, M.D.
Compliance Oversight Coordinator
Division of Human Subject Protections

cc: Mr. Daniel Beyer, IRB Executive Director, CCF
Dr. Alan Lichtin Chairperson, IRB, CCF
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