



Office for Human Research Protections
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March 7, 2005

Michael Gottesman, M.D.
Deputy Director for Intramural Research
National Institutes of Health
Building 1, Room 160
1 Center Drive
Bethesda, MD 20892

RE: Human Research Subject Protections under Federalwide Assurance FWA-5897

Dear Dr. Gottesman:

The Office for Human Research Protections (OHRP) has reviewed the November 29, 2004 and February 10, 2005 reports submitted by the National Institute of Allergy and Infectious Diseases (NIAID) in response to determinations of noncompliance with Department of Health and Human Services (HHS) regulations for the protection of human research subjects (45 CFR Part 46).

OHRP finds that the corrective actions taken by the NIAID and the National Institutes of Health (NIH) Clinical Center adequately address the determinations outlined in OHRP's October 15, 2004 letter, and are appropriate under the NIH Federalwide Assurance. OHRP anticipates no further involvement in this matter.

OHRP appreciates the continued commitment of NIAID and NIH 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.
Director, Division of Compliance Oversight

cc: Dr. Peter Mannon, NIAID
Ms. Doreen Chaitt, NIAID
Dr. Alan Sandler, NIH
Dr. Lana Skirboll, NIH
Commissioner, FDA
Dr. David Lepay, FDA

Dr. Bernard Schwetz, OHRP
Dr. Melody Lin, OHRP
Dr. Michael Carome, OHRP
Dr. Kristina Borrer, OHRP
Ms. Shirley Hicks, OHRP
Dr. Edward Bartlett, OHRP
Ms. Carol Weil, OHRP
Ms. Patricia El-Hinnawy, OHRP
Ms. Janet Fant, OHRP