



Office for Human Research Protections
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February 17, 2006

Tecla Mickoseff
CEO
Harbor-UCLA Medical Center
1000 West Carson Street
Torrance, CA 90509

RE: Human Research Subject Protections Under Multiple Project Assurance M-1301 and Federalwide Assurance FWA-2334

Research Project: Phase I/II Trial: The Safety and Immunogenicity of Live-Attenuated Varicella Vaccine (Varivax) in HIV-Infected Children

Project Number: ACTG #265

Principal Investigator:

Research Project: Phase I Trial: Safety and Effectiveness of Four Anti-HIV Drug Combinations in HIV-Infected Children and Teens

Project Number: ACTG #377

Principal Investigator: Margaret Keller, M.D.

Dear Ms. Mickoseff:

The Office for Human Research Protections (OHRP) has reviewed the Harbor-UCLA Medical Center's (HUMC) July 14, 2005 response to OHRP's June 9, 2005 letter regarding indications of possible noncompliance with Department of Health and Human Services (HHS) regulations for the protection of human research subjects (45 CFR part 46) involving the above-referenced research.

Based upon its review, OHRP finds that HUMC has addressed the concerns raised in OHRP's June 9, 2005 letter. In particular, OHRP notes the HUMC report stated that ACTG #265 did not include wards of the state, and ACTG #377 included wards of the state but was determined by the institutional review board at its December 9, 1997 meeting to fall under HHS regulations at 45 CFR 46.405. As a result, there should be no need for further involvement of OHRP in this matter.

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,

Patrick J. McNeilly, Ph.D.
Compliance Oversight Coordinator
Division of Compliance Oversight

cc: Dr. Stewart A. Laidlaw, Director, Compliance and Regulatory Affairs, HUMC
Dr. Kenneth R. Huff, Chairperson, John F. Wolf Human Subjects Committee IRB #1
Dr. Michael Smith, Chairperson, John F. Wolf Human Subjects Committee IRB #2
Commissioner, FDA
Dr. David Lepay, FDA
Dr. Lana Skirboll, NIH
Dr. Anthony Fauci, NIH
Dr. Edmund C. Tramont, NIH
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Ms. Patricia El-Hinnawy, OHRP
Ms. Janet Fant, OHRP