DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

Office for Human Research Protections
The Tower Building
1101 Wootton Parkway, Suite 200
Rockville, Maryland 20852

Telephone: 240-453-8238
FAX: 240-453-6909
E-mail: kcooper@osophs.dhhs.gov

February 17, 2005

John J. Lucas, Ph.D.
Vice Provost for Research
SUNY Upstate Medical University
Research Administration
750 East Adams Street
Room 1254 WH
Syracuse, NY 13210

RE: Human Research Subject Protections Under Federalwide Assurance FWA-5967

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: Coleen K. Cunningham, M.D.

Dear Dr. Lucas:

The Office for Human Research Protections (OHRP) has reviewed SUNY Upstate Medical University's (SUNYUMU) June 21, 2005 response to OHRP's June 13, 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 makes the following determination regarding the above-referenced research:

(1) HHS regulations at 45 CFR 46.404-409 require specific findings on the part of the IRB for approval of research involving children. OHRP's review of SUNYUMU IRB documents for the above-referenced research revealed no evidence that the IRB considered and made the required findings when reviewing this research involving children.

OHRP acknowledges SUNYUMU's statement in its June 21, 2005 response: "ACTG #265 was approved under subpart D category 45 CFR 46.404 (control group) and 45 CFR 46.405 (treatment group)." However, OHRP found no evidence in the materials reviewed to support this statement.

Corrective Actions: OHRP acknowledges SUNYUMU's statement in its June 21, 2005 response:

> Over the last several years, the IRB has been using a 'Checklist for Research on Children' which documents risk level, benefits, requirements for permission by parents/guardians and assent. This checklist mirrors the requirements of 45 CFR 46 subpart D. In addition, the Upstate IRB has been using a much improved IRB application form which elicits detailed information about the consent process, recruitment of study subjects, and the safeguards which will be implemented to protect the rights and welfare of vulnerable subjects.

OHRP notes that the above-referenced subpart D checklist and improved IRB application were not included in the materials sent to OHRP.

Required Action: By March 31, 2006, please provide a satisfactory corrective action plan to specifically address the above finding. OHRP requests that SUMYUMU provide a copy of the checklist and the current IRB application, as well as copies of recent IRB minutes which demonstrate the use of these materials.

In addition, OHRP has the following concerns:

(2) [Redacted]

[Redacted]

Please forward your response to the above finding and concerns so that OHRP receives it no later than March 17, 2006.

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,

Karena Cooper, J.D., M.S.W.
Compliance Oversight Coordinator
Division of Compliance Oversight

cc: Marti B. Benedict, IRB Admin./Chief Compliance Ofcr. for Research, SUNY Upstate Med U
Dr. Ronald L. Dubowy, Chairperson, IRB #1, SUNY Upstate Med U
Commissioner, FDA
Dr. David Lepay, FDA
Dr. Lana Skirboll, NIH
Dr. Anthony Fauci, NIH
Dr. Edmund C. Tramont, NIH
Ms. Donna Marchigiani, NIH
Dr. Robinsue Frohboese, OCR
Dr. Bernard Schwetz, OHRP
Dr. Melody H. Lin, OHRP
Dr. Michael Carome, OHRP
Ms. Shirley Hicks, OHRP
Dr. Irene Stith-Coleman, OHRP

Dr. Kristina Borror, OHRP
Ms. Patricia El-Hinnawy, OHRP
Ms. Janet Fant, OHRP