DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

Office for Human Research Protections
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February 17, 2006

Judy F. Matuk, M.S.
Director, Research Compliance
SUNY Health Science Center, Stony Brook
Office of Research Compliance
Stony Brook, NY 11794-3368

RE: Human Research Subject Protections Under Federalwide Assurance FWA-125

Research Project: Phase I Study: A Double-Blind Placebo-Controlled Trial of the Safety and Immunogenicity of a Seven Valent Pneumococcal Conjugate Vaccine in Presumed-HIV-Infected Infants (ACTG #292)
Project Number: 95-2372 (UHRC 95-128)
Principal Investigator: Sharon A. Nachman, M.D.

Research Project: A Phase II Rolling Arm Master Protocol (PRAM) of Novel Antiretroviral Therapy In Stable Experienced HIV-Infected Children/PRAM2 (ACTG #377)
Project Number: 97-295 (UHRC 97-115)
Principal Investigator: Sharon A. Nachman, M.D.

Dear Ms. Matuk:

The Office for Human Research Protections (OHRP) has reviewed the SUNY Health Science Center, Stony Brook's (SUNY-SB) July 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 of noncompliance regarding the above-referenced research:

> HHS regulations at 45 CFR 46.404-409 require specific findings by the institutional review board (IRB) for approval of research involving children. With respect to the ACTG #377, approved by the SUNY-SB IRB on January 26, 1998, OHRP finds no evidence that the IRB considered the requirements of HHS regulations at 45 CFR 46.401-499 (Subpart D) in its initial review and approval of the research in 1998, including

approval of the research under one of the permissible research categories set forth at 45 CFR 46.404-407.

OHRP acknowledges that the minutes of the SUNY-SB IRB regarding the December 16, 1999 continuing review of ACTG #377 document the IRB's consideration of the requirements of subpart D, including IRB approval of the research under 45 CFR 46.405.

With respect to ACTG #292, OHRP finds no evidence that the IRB ever considered the requirements of HHS regulations at 45 CFR 46.400-409 in its review of this research.

Corrective Action: Since December of 1999, the SUNY-SB IRB has consistently cited in meeting minutes the subpart D category under which each research study involving children was approved (45 CFR 46.404 through 46.407). In addition, compliance with subpart D requirements is communicated to investigators in either the "modifications required" or approval letters. SUNY-SB's stated policy for studies approved under 45 CFR 46.406 is that the IRB will require investigators to contact the IRB before enrollment of any ward. SUNY-SB is also providing in-service education to IRB members regarding the requirements of 45 CFR 46.409.

OHRP finds that these corrective actions adequately address the above determinations and are appropriate under the SUNY-SB FWA. As a result, there should be no need for further involvement of OHRP in this matter, unless SUNY-SB uncovers additional facts that indicate possible noncompliance with the HHS regulations.

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,

Carol J. Weil, J.D.
Compliance Oversight Coordinator
Division of Compliance Oversight

cc: Mary A. Johnson, Coordinator, Research Compliance, SUNY Stony Brook
Dr. Harold E. Carlson, Chairperson, IRB #1, SUNY Stony Brook
Dr. Michael L. Pearl, Chairperson, IRB #2, SUNY Stony Brook
Dr. David Lepay, FDA
Dr. Lana Skirboll, NIH
Dr. Anthony Fauci, NIH
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