DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

Office for Human Research Protections
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July 21, 2006

Myrna Boissen
Executive Director
San Juan Hospital
P.O. Box 21405
San Juan, PR 00928-1405

**RE: Human Research Subject Protections Under Cooperative Agreement T-3478 and Federalwide Assurance (FWA) 9049**

**Research Project: Phase I Safety Trial: A Placebo-Controlled, Phase I Clinical Trial to Evaluate the Safety and Immunogenicity of Recombinant Envelope Proteins of HIV-1 gp160 and gp120 in Children ≥1 Month Old with Asymptomatic HIV Infection**
**Project Number: ACTG #218**
**Principal Investigator: Eleanor Jiménez, M.D.**

Dear Ms. Boissen:

The Office for Human Research Protections (OHRP) has reviewed the San Juan Hospital's (SJH) July 13, 2006 response to OHRP's June 19, 2006 letter regarding the above-referenced research.

In its June 19, 2006 letter, OHRP found that the SJH institutional review board (IRB) failed to obtain sufficient information regarding additional safeguards that have been included in the study to protect the rights and welfare of subjects who were likely to be vulnerable to coercion or undue influence, as required by Department of Health and Human Services regulations at 45 CFR 46.111(b). In specific, OHRP found that the SJH IRB did not receive sufficient information regarding such safeguards with respect to the enrollment of wards of the state or foster children in ACTG #218.

**Corrective Action:** SJH has developed a written procedure which describes the steps which will be taken to ensure that an advocate for wards of the state is identified, where necessary. The procedure also outlines the identification of legal guardians of wards and foster children and who may enroll subjects in research. In addition, the procedure also includes steps to ensure that the

SJH IRB adequately reviews information relating to the extent to which wards are to be enrolled in research. OHRP also notes that SJH has provided training to its investigators regarding the enrollment of wards or foster children in research.

OHRP finds these corrective actions to be adequate and appropriate under the SJH FWA. 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 these determinations.

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. Ana Barletta, Medical Director, SJCH
Dr. Luis Medina, IRB Chair, SJCH
Commissioner, FDA
Dr. David Lepay, FDA
Dr. Sam Shekar, NIH
Dr. Anthony Fauci, NIH
Dr. Edmund C. Tramont, NIH
Ms. Donna Marchigiani, NIH
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Ms. Patricia El-Hinnawy, OHRP
Ms. Carla Brown, OHRP