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: 240-453-8141
FAX: 301-402-2071
E-mail: jgorey@osophs.dhhs.gov

February 17, 2006

Frank Tiedemann
President / CEO
Children's Hospital & Research Center at Oakland
747 Fifty-second Street
Oakland, CA 94609

RE: Human Research Subject Protections Under Federalwide Assurance FWA-94

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: Ann Petru, M.D.

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
Project Number: ACTG #292
Principal Investigator: Ann Petru, M.D.

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: Ann Petru, M.D.

Dear Mr. Tiedemann:

The Office for Human Research Protections (OHRP) has reviewed the Children's Hospital & Research Center at Oakland's (CHRCO) July 14, 2005 response to OHRP's June 10, 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.

OHRP notes that your report indicated that ACTG #265 did not include wards of the state. In addition, your report indicated that ACTG #218, #292 and #377 included wards of the state but were determined by the CHRCO institutional review board (IRB) to fall under HHS regulations at 45 CFR 46.405.

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 institutional review board (IRB) for approval of research involving children. OHRP's review of CHRCO IRB documents for the above-referenced research revealed little evidence that the CHRCO IRB considered and made the required findings when reviewing this research involving children.

OHRP notes that one ward was involved in ACTG #218, and that this subject was not recruited at your institution; however, OHRP is unable to find any reference to the specific findings required under HHS regulations at 45 CFR 46.404-409 in IRB minutes for this study. ACTG #292 and #377 included wards and were determined by the IRB to fall under HHS regulations at 45 CFR 46.405.

OHRP acknowledges the December 1989 CHRCO Advocacy Policy, a document that specifies the responsibilities of the advocate required in research involving children who are wards of the state in accordance with HHS regulations at 45 CFR 46.409.

Required Action: By March 31, 2006, please submit to OHRP a satisfactory corrective plan to specifically address the above finding.

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 31, 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,

Julia Gorey, J.D.
Division of Compliance Oversight

cc: Mordechai D. Pelta, IRB Administrator, Children's Hosp & Research Ctr at Oakland
Dr. John R. Waterson, Chairperson, Children's Hosp Oakland IRB #1
Dr. Lana Skirboll, NIH
Dr. Anthony Fauci, NIH
Dr. Edmund C. Tramont, NIH
Ms. Donna Marchigiani, NIH
Dr. Robinsue Frohboese, OCR
Commissioner, FDA
Dr. David Lepay, FDA
Dr. Bernard Schwetz, OHRP
Dr. Melody H. Lin, OHRP
Dr. Michael Carome, OHRP
Dr. Kristina Borror, OHRP
Ms. Shirley Hicks, OHRP
Dr. Irene Stith-Coleman, OHRP
Ms. Patricia El-Hinnawy, OHRP
Ms. Janet Fant, OHRP