DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

Office for Human Research Protections
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June 19, 2006

Philip V. Spina, M.A., C.R.A.
Administrative Director
Children's Memorial Hospital
2300 Children's Plaza
Chicago, IL 60614-3394

RE: Human Research Subject Protections Under Multiple Project Assurance M-1484 and Federalwide Assurance FWA-1011

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: Ram Yogev, 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: Ram Yogev, M.D.

Dear Mr. Spina:

The Office for Human Research Protections (OHRP) has reviewed the Children's Memorial Hospital's (CMH) March 29, 2006 response to OHRP's February 17, 2006 letter regarding the above-referenced research.

Department of Health and Human Services (HHS) regulations at 45 CFR 46.111(b) require that when some or all of the subjects (e.g., children) are likely to be vulnerable to coercion or undue influence, the institutional review board (IRB) must determine that additional safeguards have been included in the study to protect the rights and welfare of these subjects. In its February 17,

2006 letter, OHRP raised a concern that the CMH IRB records appeared to demonstrate a failure of the IRB to obtain sufficient information regarding such safeguards with respect to the enrollment of wards of the state or foster children. After reviewing your report, OHRP notes that CMH had in place a memorandum of understanding (MOU) with the Illinois Department of Children and Family Services (IDCFS) which outlined a procedure for further review of research involving wards by IDCFS. Under the MOU, the IDCFS case manager is also required to review the child's condition and approve the study. OHRP also notes that CMH has also taken steps to update its MOU with IDCFS to include greater safeguards with respect to confidentiality, consenting and notification requirements, and involvement of case managers. OHRP finds that this response has adequately addressed the concern raised in its February 17, 2006 letter. 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: Tricia N. Becker, Assistant Director, Children's Memorial Hospital
Dr. Vita J. Land, Chairperson, Children's Memorial Hospital IRB #1
Commissioner, FDA
Dr. David Lepay, FDA
Dr. Sam Shekar, NIH
Dr. Anthony Fauci, NIH
Dr. Edmund C. Tramont, NIH
Ms. Donna Marchigiani, NIH
Dr. Robinsue Frohboese, OCR
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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