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, 2005

Daniel H. Winship
Chief
Cook County Bureau of Health Services
1900 West Polk Street
Suite 220
Chicago, IL 60612

RE: Human Research Subject Protections Under Multiple Project Assurance M-1150 and Federalwide Assurance FWA-1802

Research Project: Phase I/II Study: Ritonavir Therapy in HIV-I Infected Infants and Children
Project Number: ACTG #345
Principal Investigator: Kenneth Boyer, 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: Kenneth Boyer, M.D.

Dear Mr. Winship:

The Office for Human Research Protections (OHRP) has reviewed the Cook County Bureau of Health Services' (CCBHS) July 1, 2005 response to OHRP's June 9, 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 Institutional Review Board (IRB) for approval of research involving children. OHRP's

review of CCBHS 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 the following statement in CCBHS's letter dated July 1, 2005 regarding the two studies referenced above: "In both cases, the protocol was approved for the vulnerable population of children under 45 CFR 46.405 for the potential benefit of the subjects themselves." OHRP also acknowledges the following statement regarding ACTG #377: "This protocol included a sub-study, which was named ACTG 377/727 which was approved under 45 CFR 46.404 (minimal risk.)" However, OHRP found no evidence in any of the material it reviewed to support the institution's statements.

Required Action: By March 31, 2006, please provide a satisfactory corrective action 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,

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

cc: Lynda Brodsky, Director, Research Affairs, Cook County Bureau of Health Services
Dr. Peter Orris, Chairperson, John H. Stoger Hosp Cook Co IRB #1
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