



Office for Human Research Protections
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February 17, 2006

Steve Anderman
Senior Vice President/Chief Operating Officer
Bronx-Lebanon Hospital Center
1650 Grand Concourse
Bronx, NY 10457

**RE: Human Research Subject Protections Under Multiple Project Assurance M-1518
and Federalwide Assurance FWA-1632**

**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: Andrew Wiznia, M.D.

Dear Dr. Anderman,

The Office for Human Research Protections (OHRP) has reviewed the Bronx-Lebanon Hospital Center's (BLHC) September 8 and September 12, 2005 responses 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 #292 and #345 did not include wards of the state; ACTG #377 included wards of the state but was determined by the BLHC 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 IRB for approval of research involving children. OHRP's review of BLHC IRB documents for the above-referenced research revealed no evidence that the BLHC IRB considered and made the required findings when reviewing this research involving children.

OHRP acknowledges that BLHC stated in its September 8, 2005 response that the above-referenced research trial was approved by the BLHC IRB under HHS regulations at 45 CFR 46.405. However, OHRP has found no evidence in the materials reviewed to support this statement.

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 concern:

(2) [Redacted]

Please forward your response to the above finding and concern 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: Dr. Murli Purswani, FAAP, Chief, Division of Pediatric Infectious Diseases
Dr. Stephen Schultz, HPA and IRB #1 Chairperson, Bronx-Lebanon Hosp. Ctr.
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 Borrer, OHRP
Ms. Shirley Hicks, OHRP
Dr. Irene Stith-Coleman, OHRP
Ms. Patricia El-Hinnawy, OHRP
Ms. Janet Fant, OHRP