



Office for Human Research Protections
The Tower Building
1101 Wootton Parkway, Suite 200
Rockville, Maryland 20852

Telephone: 240-453-8132
FAX: 240-453-6909
E-mail: kborrow@osophs.dhhs.gov

February 17, 2006

James Hendricks, Ph.D.
Vice President for Research
Children's Hospital and Regional Medical Center
Hospital Administration CH-01
4800 Sand Point Way NE
P.O. Box 5371
Seattle, WA 98105-0371

RE: Human Research Subject Protections Under Multiple Project Assurance M-1214 and FederalWide Assurance FWA-2443

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: Lisa M. Frenkel, M.D.

Dear Dr. Hendricks:

The Office for Human Research Protections (OHRP) has reviewed the Children's Hospital and Regional Medical Center's (CHRMC) 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 reports indicated that ACTG #265 did not include wards of the state. In addition, your reports indicated that ACTG #377 included wards of the state but were determined by the CHRMC institutional review board (IRB) to fall under HHS regulations at 45 CFR 46.405.

Based upon its review, OHRP makes the following determinations 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 acknowledges CHRMC's statement in its July 14, 2005 response that "Children's IRB approved this project under category 45 CFR 46.405....The IRB application file and the minutes for this study do not document that the IRB approved the research under category 45 CFR 46.405." OHRP's review of

CHRMC IRB documents for the above-referenced research revealed no other evidence that the CHRMC IRB considered and made the required findings when reviewing this research involving children.

Required Action: Please provide a corrective action plan that adequately addresses the above finding.

OHRP has the following additional concerns regarding the above-referenced research:

(2) [Redacted]

Please forward your responses to the above required actions and concerns so that OHRP receives them 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,

Kristina C. Borrer, Ph.D.
Director, Division of Compliance Oversight

cc: Elizabeth Trias, HPA, Children's Hospital & Regional Med. Ctr.
Dr. Douglas Diekema, IRB Chairperson
Commissioner, FDA
Dr. David Lepam, 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
Ms. Patricia El-Hinnawy, OHRP
Ms. Janet Fant, OHRP