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, 2006

Robert A. Saporito, D.D.S.
Executive Sr. Vice President, Academic Affairs
University of Medicine and Dentistry of New Jersey
65 Bergen Street, SSB 1441
Newark, NJ 07107

RE: Human Research Subject Protections Under Federalwide Assurance FWA-1861

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: Sunandra Gaur, M.D.

Dear Dr. Saporito:

The Office for Human Research Protections (OHRP) has reviewed the University of Medicine and Dentistry of New Jersey's (UMDNJ) August 29, 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.

OHRP notes that your report indicated that ACTG #265 did not include wards of the state. In addition, your report indicated that ACTG #377 included two wards of the state.

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

Corrective Action: The August 29, 2005 response to OHRP acknowledged that appropriate determinations required under HHS regulations at 45 CFR part 46, subpart D, were not made by the IRB for this research. OHRP acknowledges that the UMDNJ instituted in 2001 a Human Subjects Protection Program for education and training of all individuals involved in the conduct of research with human subjects. The IRB infrastructure was reorganized, with the creation of a Human Subjects Protection Program. New documentation standards were put into place, with required documentation of determinations required under HHS regulations at 45 CFR part 46, subpart D, for every study involving children since 2002. Systematic improvements have continued beyond regulatory requirements, including implementation of best practice standards.

The August 29, 2005 response to OHRP specified that actions taken after June 2005 included adding additional quarterly investigator training outlining specific requirements for research involving children, including enrollment of wards of the state, consistent with the requirements of HHS regulations at 45 CFR 46.409. All IRB members were provided with OHRP guidance on subpart D of 45 CFR part 46, with special emphasis on investigators enrolling wards of the state and the additional determinations required. Language was added to approval notices to alert investigators enrolling pediatric subjects that wards require additional protections.

OHRP finds that these corrective actions adequately address the above finding and are appropriate under the UMDNJ FWA.

In addition, OHRP has the following concern:

(2) [Redacted]

[Redacted]

Please forward your response to the above 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
Division of Compliance Oversight

cc: Ms. Barbara J. LoDico, HPA, UMDNJ
Dr. Mary E. Swigar, UMDNJ-R. W. Johnson Med Sch IRBs #1 - #5 Chairperson
Dr. Gintare T. Gecys, UMDNJ Sch Osteopathic Med IRB #1 Chairperson
Dr. Cheryl Kennedy, UMDNJ New Jersey Med Sch IRBs #1 - #4 Chairperson
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