DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

Office for Human Research Protections
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October 28, 2002

Zerababel M. Nyiira, Ph.D.
Secretary
Uganda National Council of
Science and Technology
Plot 10, Kampala Road
Uganda House, 11th Floor
P.O. Box 6884
Kampala, Uganda

Nelson K. Sewankambo, M.D.
Uganda National Council of
Science and Technology
Makerere Medical School
P.O. Box 7072
Kampala, Uganda

RE: Human Research Subject Protections Under Federalwide Assurance (FWA) 00001293, Single Project Assurances (SPA) S-6233 and S-6234, and Cooperative Project Assurances (CPA) T-5124 and T-5125

Research Project: **A Phase III Efficacy Trial of Oral AZT vs. Oral Nevirapine in HIV-1 Infected Pregnant Ugandan Women (HIVNET 012)**
Principal Investigator: Professor Francis Mmiro

Dear Dr. Nyiira and Dr. Sewankambo:

The Office for Human Research Protections (OHRP) has reviewed your reports dated August 20, 2002 and August 29, 2002 submitted in response to OHRP's July 16, 2002 letter regarding the above-referenced research and your institution's system for the protection of human subjects.

OHRP acknowledges the efforts of the AIDS Research Committee (ARC) to address the issues raised in its July 16, 2002 letter. OHRP finds that the ARC has developed a satisfactory corrective action plan to address the issues raised in OHRP's July 16, 2002 letter. Among the corrective action noted in your reports are the following:

(a) The ARC has conducted an audit of all ongoing Department of Health and Human Services (HHS) supported research involving human subjects to ensure that all studies had undergone Institutional Review Board (IRB) review and approval and have appropriately suspended all research studies which had not had proper IRB approval.

(b) By December 2002, the ARC will establish administrative procedures to ensure its proper functioning. This action will include the hiring of a regulatory affairs officer.

(c) By December 2002, the ARC will develop detailed operational guidelines for its functions.

(d) The ARC has developed an adequate plan to educate all research investigators, IRB members, and all IRB staff on an ongoing basis about the ethical principles and regulatory requirements for the protection of human subjects.

(e) The ARC has committed to ensure that investigators provide details of research studies in language understandable to all study participants.

(f) By October 2002, the ARC will ensure that it will have a non-scientist as a member of the committee.

Required Action: By December 31, 2002, the ARC must provide OHRP with a report on the status of its implementation of its corrective action plan. This report should include the following:

(a) A status report on the implementation of each proposed corrective action in your August 29, 2002 letter.

(b) A summary of the IRB's progress in reviewing all suspended research projects.

(c) Copies of minutes for three meetings between September and December 2002.

(d) A copy of any revised written IRB policies and procedures.

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: Dr. Edward K. Mbiode, IRB Chair
Professor Francis Mmiro, MU
Dr. Michael Klag, Johns Hopkins University
Dr. Brooks Jackson, Johns Hopkins University
Dr. Willard Cates, Family Health International
Commissioner, FDA
Dr. David Lepay, FDA
Dr. Mary Anne Luzar, NIH/NIAID
Dr. Edmond Tramont, NIH/NIAID
Mr. John Tierney, NIH/NIAID
Dr. Greg Koski, OHRP
Dr. Melody H. Lin, OHRP
Dr. Michael Carome, OHRP
Mr. George Gasparis, OHRP
Dr. Jeffrey Cohen, OHRP
Ms. Yvonne Higgins, OHRP
Mr. Barry Bowman, OHRP