DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

Office for Human Research Protections
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March 24, 2003

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 the AIDS Research Committee's

(ARC) report dated March 11, 2003 submitted in response to OHRP's October 28, 2002 letter regarding the above-referenced research and your institution's system for the protection of human subjects. OHRP acknowledges the following additional corrective actions taken by the ARC:

(1) The hiring of a regulatory affairs officer to assist with records keeping and documentation of ARC proceedings.

(2) Development of additional operational guidelines for the function of the ARC.

(3) Expansion of educational opportunities for ARC members and researchers in research ethics and good clinical practices.

(4) Appointment of a non-scientist as a member of the ARC.

As a result of the above corrective actions there should be no need for further involvement of OHRP in this matter. Of course, OHRP must be notified should new information be identified which might alter this determination.

At this time OHRP would like to provide the following additional guidance:

(1) Department of Health and Human Services (HHS) regulations at 45 CFR 46.115(a)(2) require that the minutes of IRB meetings document the vote on all institutional review board (IRB) actions including the number of members voting for, against, and abstaining. In order to document the continued existence of a quorum, OHRP recommends that votes be recorded in the minutes using the following format: Total = 15; Vote: For-14, Opposed-0, Abstained-1 (NAME).

(2) Written IRB policies and procedures should provide a step-by-step description with key operational details for each of the procedures required by HHS regulations at 45 CFR 46.103(b)(4) and (5). Enclosed please find a copy of OHRP's most recent guidance on written IRB procedures. This document may also be obtained on OHRP's website at http://ohrp.osophs.dhhs.gov/humansubjects/guidance/irb71102.pdf.

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

Enclosure

cc with enclosure:
Dr. Edward K. Mbidde, IRB Chair
Professor Francis Mmiro, MU

cc without enclosure:
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
Dr. Bernard Schwetz, OHRP
Dr. Melody H. Lin, OHRP
Dr. Michael Carome, OHRP
Dr. Kristina Borror, OHRP
Mr. George Gasparis, OHRP
Ms. Shirley Hicks, OHRP
Ms. Yvonne Higgins, OHRP
Ms. Melinda Hill, OHRP