DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

Office for Human Research Protections
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January 5, 2005

Ronald E. Struxness, M.H.A.
Chief Executive Officer
Saint Joseph Hospital
2900 North Lake Shore Drive
Chicago, Illinois 60657

RE: Human Research Subject Protections Under Federalwide Assurances FWA-4282 and FWA-2823

Research Project:	A Randomized, Open-Label Study of the Impact of Two Doses of Subcutaneous Recombinant IL-2 (Proleukin) on Viral Burden and CD4+ Cell Count in Patients with HIV-1 Infection and CD4+ Cell Counts $\geq$ 300/mm^3
Principal Investigator:	Roberta Luskin-Hawk, M.D.
Project Number:	CPCRA 059
HHS Award Number:	2U01 AI42199-09

Dear Mr. Struxness:

The Office for Human Research Protections (OHRP) has reviewed your November 8, 2004 report in response to OHRP's August 26, 2004 letter regarding the above-referenced research and the policies and procedures of the Saint Joseph Hospital (SJH) Institutional Review Board (IRB). OHRP has determined that the corrective actions summarized in your November 8, 2004 report appropriately address the findings in items (6)-(10) as described in OHRP's letter of August 26, 2004, and are appropriate under SJH's Assurance.

As a result, there should be no need for further involvement of OHRP in this matter. However, OHRP must be notified should new information be identified which might alter this determination.

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

(1) Department of Health and Human Services (HHS) regulations at 45 CFR 46.107(e) stipulate that no IRB member may participate in the IRB's initial or continuing review of a project in which the member has a conflicting interest, except to provide information requested by the IRB. OHRP recommends that except when requested by the IRB to be present to provide information, IRB members leave the meeting room when the IRB reviews research in which they have a conflicting interest, and such should be noted in the IRB meeting minutes.

(2) OHRP recommends that the written IRB procedures provide a description of which office(s) or institutional official(s) is responsible for promptly reporting to the IRB, appropriate institutional officials, any supporting agency or department heads, and OHRP of (i) any unanticipated problems involving risks to subjects or others; (ii) any serious or continuing noncompliance with 45 CFR part 46 or the requirements or determinations of the IRB; and (iii) any suspension or termination of IRB approval.

OHRP appreciates the commitment of SJH to the protection of human research subjects. Please do not hesitate to contact me should you have any questions.

Sincerely,

Robert J. Meyer
Compliance Oversight Coordinator
Division of Compliance Oversight

cc: Dr. Roberta Luskin-Hawk, President, AIDS Research Alliance - Chicago
Mr. Edward M. Goodwin, AIDS Research Alliance - Chicago
Dr. David M. Berkson, IRB Chair, Saint Joseph Hospital
Commissioner, FDA
Dr. David A. Lepay, FDA
Dr. Bernard A. Schwetz, OHRP
Dr. Melody H. Lin, OHRP
Dr. Michael A. Carome, OHRP
Dr. Kristina Borror, OHRP

Ms. Shirley Hicks, OHRP
Ms. Patricia El-Hinnawy, OHRP
Ms. Janet Fant, OHRP