



Office for Human Research Protections
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February 17, 2006

Michael Dowling, M.S.W.
President/COO
North Shore-Long Island Jewish Health System
143 Community Drive
Great Neck, NY 11021

**RE: Human Research Subject Protections Under Multiple Project Assurance
M-1302 and Federalwide Assurances FWA-2505**

**Research Project: Pram 2 – A Phase I/II Randomized Multicenter Protocol
Comparing Four Antiretroviral Regimens Containing Combinations of Protease
Inhibitors, NRTIs and NNRTI
Project Number: ACTG #377
Principal Investigator: Dr. Savita Pahwa**

**Research Project: Phase I Safety Trial: A Placebo-Controlled, Phase I Clinical Trial
to Evaluate the Safety and Immunogenicity of Recombinant Envelope Proteins of
HIV-1 gp160 and gp120 in Children \geq 1Month Old with Asymptomatic HIV
Infection
Project Number: ACTG #218**

**Research Project: Phase I/II Study: Ritonavir Therapy in HIV-I Infected Infants
and Children
Project Number: ACTG #345
Principal Investigator: Dr. Savita Pahwa**

Dear Mr. Dowling:

The Office for Human Research Protections (OHRP) has reviewed the North Shore-Long Island Jewish Health System's (NSLIJHS) July 20, 2005 response to OHRP's June 13, 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.

Based upon its review, OHRP finds that NSLIJHS has addressed the concerns raised in OHRP's June 13, 2005 letter. In particular, OHRP notes the NSLIJHS report stated that ACTG #218 was not conducted at your institution, ACTG #345 did not include wards of the state, and ACTG #377 included wards of the state but was determined by the institutional review board at its November 20, 1997 meeting to fall under HHS regulations at 45 CFR 46.405. As a result, there should be no need for further involvement of OHRP in this matter.

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: Jacki Altman, HPA, North Shore University Hospital
Dr. Martha Arden, Chair, Long Island Jewish Medical Center IRB #1
Dr. Martin Lesser, Chair, North Shore University Hospital IRB #2
Commissioner, FDA
Dr. David Lepad, FDA
Dr. Lana Skirboll, NIH
Dr. Anthony Fauci, NIH
Dr. Edmund C. Tramont, NIH
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Dr. Robinsue Frohboese, OCR
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Ms. Janet Fant, OHRP