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, 2005

Judith Argon
Vice President, Research Administration
Children's Hospital of Philadelphia
Abramson Research Center, First Floor
Philadelphia, PA 19104

RE: Human Research Subject Protections Under Federalwide Assurance FWA-459

Research Project: Phase I Safety Trial: A Study to Test the Safety of Recombinant Interleukin-2 (rIL-2) in HIV- Infected Children
Project Number: ACTG #299
Principal Investigator: Stuart Starr, M.D.

Dear Ms. Argon:

The Office for Human Research Protections (OHRP) has reviewed Children's Hospital of Philadelphia's (CHOP) July 13, 2005 response to OHRP's June 10, 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 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 CHOP IRB documents for the above-referenced research revealed no evidence that the CHOP IRB considered and made the required findings when reviewing this research involving children.

OHRP acknowledges the following statement included in CHOP's July 13, 2005 letter: "A review of the minutes reveals that Subpart D was not specifically mentioned in the IRB minutes for this protocol. Therefore, it is not known definitively under which Subpart D

category the protocol was approved. We assume, however, that the IRB believed that the study could provide direct benefit to the enrolled child and that the IRB considered the protocol approvable under 406 [*sic*]."

Required Action: By March 31, 2006, please provide a satisfactory corrective action plan to specifically address the above finding.

In addition, OHRP has the following concerns:

(2) [Redacted]

Please forward your response to the above finding and concerns so that OHRP receives it no later than March 31, 1006.

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,

Karena Cooper, J.D., M.S.W.
Compliance Oversight Coordinator
Division of Compliance Oversight

cc: Barbara Bayton, HPA, Children's Hospital of Phil.
Dr. Ronald Rubenstein, Chairperson, IRB #1- #3
Lynn Bevan, CHOP
Dr. Steven Douglas, CHOP
Carol Vincent
Commissioner, FDA
Commissioner, FDA
Dr. David Lepay, FDA
Dr. Lana Skirboll, NIH
Dr. Anthony Fauci, NIH
Dr. Edmund C. Tramont, NIH
Ms. Donna Marchigiani, NIH
Dr. Robinsue Frohboese, OCR
Dr. Bernard Schwetz, OHRP
Dr. Melody H. Lin, OHRP
Dr. Michael Carome, OHRP
Ms. Shirley Hicks, OHRP
Dr. Irene Stith-Coleman, OHRP
Dr. Kristina Borror, OHRP
Ms. Patricia El-Hinnawy, OHRP
Ms. Janet Fant, OHRP