



FOR US POSTAL SERVICE DELIVERY:

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March 30, 2001

Arthur W. Nienhuis, M.D.
Director
St. Jude Children's Research Hospital
332 North Lauderdale Street
Memphis, TN 38105-2794

RE: Human Research Subject Protections Under Multiple Project Assurance (MPA) M-1013

Research Project: Total Therapy Study XIV for Newly Diagnosed Patients with Acute Lymphoblastic Leukemia (ALL)

Principal Investigator: Dr. Ching-Hon Pui

HHS Support: R01 CA78224, P30 CA21765, and R37 CA36401

Dear Dr. Nienhuis:

The Office for Human Research Protections (OHRP), formerly the Office for Protection from Research Risks (OPRR), has reviewed your March 30, June 9, and June 27, 2000 reports regarding the above referenced research project and St. Jude Children's Research Hospital's (SJCRH's) systemic protections for human subjects.

Based upon its review of your reports, OHRP finds that SJCRH has adequately addressed all findings and concerns regarding the above referenced research and implemented all required actions stipulated by OPRR's November 5, 1999 letter.

As a result, 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.

March 30, 2001

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,



Michael A. Carome, M.D.

Director, Division of Compliance Oversight

cc: Dr. Victor M. Santana, IRB Chair, SJCRH
Dr. Joseph Mirro, Chief Medical Officer, SJCRH
Dr. Ching-Hon Pui, SJCRH
Commissioner, FDA
Dr. David Lepay, FDA
Dr. James F. McCormack, FDA
Ms. Joan Mauer, NCI
Dr. Malcolm Smith, NCI
Dr. Greg Koski, OHRP
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Mr. Barry Bowman, OHRP