



FOR US POSTAL SERVICE DELIVERY:

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March 29, 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

Dear Dr. Nienhuis:

The Office for Human Research Protections (OHRP), formerly the Office for Protection from Research Risks (OPRR), has reviewed your April 13, 2000 report responding to allegations of noncompliance with Department of Health and Human Services (HHS) regulations for the protection of human research subjects (45 CFR Part 46) that were presented in OPRR's March 3, 2000 letter.

The allegations involved the following:

- (1) Failure of some investigators at St. Jude Children's Research Hospital (SJCRH) to ensure that risks to subjects were minimized by using procedures which were consistent with sound research design and which did not unnecessarily expose the subjects to risk, in accordance with the requirements of HHS regulations at 45 CFR 46.111(a)(2). In specific, it was alleged that some children who were research subjects suffered significant unanticipated harms, including death, as a result of errors that occurred during or after surgical interventions.
- (2) Failure of the investigators and senior SJCRH officials to promptly report to the IRB and OPRR these serious unanticipated problems involving risks to subjects, as required by HHS regulations at 45 CFR 46.103(b)(5) and the SJCRH MPA.

Based upon OHRP's review of your April 13, 2000 report and additional records made available during OHRP's March 12-16, 2001 compliance oversight site visit, OHRP finds no evidence to substantiate the above allegations.

March 29, 2001

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.

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
Commissioner, FDA
Dr. David Lepay, FDA
Dr. James F. McCormack, FDA
Ms. Joan Mauer, NCI
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