DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

Office for Human Research Protections
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November 26, 2001

Chi Van Dang, M.D., Ph.D.
Vice Dean for Research
The Johns Hopkins University
School of Medicine
School of Medicine Administration Building, Room 124
720 Rutland Avenue
Baltimore, MD 21205-2196

RE: Human Research Subject Protections Under Multiple Project Assurance (MPA) M-1011

Research Project: Pediatric Methotrexate Protocol

Dear Dr. Dang:

The Office for Human Research Protections (OHRP) has reviewed your October 31, 2001 report responding to allegations of noncompliance with Department of Health and Human Services (HHS) regulations for the protection of human subjects (45 CFR Part 46) that were presented in OHRP's letter of August 16, 2001 regarding the above-referenced research.

The allegations involved the following:

(1) Failure of the investigators to ensure that risks to subjects were minimized as required by HHS regulations at 45 CFR 46.111(a)(1). In specific, it was alleged that the investigators (i)

administered high dose methotrexate to a pediatric subject whose cancer was in remission; and (ii) conducted the research in an environment where possible contact with infectious agents was not minimized.

(2) Failure of the investigators to obtain and document legally effective informed consent in accordance with the requirements of HHS regulations at 45 CFR 46.116 and 46.117. In specific, it was alleged that the informed consent document for the above referenced research failed to include the possibility of contracting fungal infections as a result of participation in the research.

Based upon OHRP's review of your October 31, 2001 report, OHRP finds no evidence to substantiate the above allegations. In specific, OHRP notes that the allegation involved clinical care and not human subject research. Such care falls outside the scope of HHS regulations for the protection of human subjects.

As a result of the above determination, 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,

Patrick J. McNeilly, Ph.D.
Compliance Oversight Coordinator
Division of Compliance Oversight

cc: Mr. Ronald R. Peterson, President, The Johns Hopkins Hospital
Dr. Sue K. Donaldson, Dean, School of Nursing, JHU
Dr. Jacquelyn Campbell, School of Nursing, JHU
Ms. Karen Cox, Research Administrator, Kennedy Krieger Institute
Dr. Darrell R. Abernethy, Clinical Director, NIA
Mr. Richard P. Suess, Chief of Staff, Applied Physics Laboratory
Mr. David Grant, Applied Physics Laboratory
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Ms Roslyn Edson, OHRP