DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

Office for Human Research Protections
The Tower Building
1101 Wootton Parkway, Suite 200
Rockville, Maryland 20852
Telephone: 301-435-0062
FAX: 301-402-2071

May 16, 2002

Lisa Tuel, M.S.
Vice President for Research
Parker Hughes Institute
2699 Patton Road
St. Paul, Minnesota 55113

**RE: Human Research Subject Protections Under Single Project Assurance (SPA) S-14934-02**
**Research Project: TXU-PAP for the Treatment of Aids**
**Principal Investigator: Dr. Fatih M. Uckun**
**DHHS Project Number: 1 RO1 AI44671**

Dear Ms. Tuel:

The Office for Human Research Protections (OHRP), formerly the Office for Protection from Research Risks (OPRR), has reviewed your April 6, 2000 report that was submitted in response to OPRR's February 25, 2000 letter regarding allegations of possible noncompliance with the Department of Health and Human Services (HHS) regulations involving the above-referenced research. Specifically, the allegations concerned the Hughes Institute's (HI's) possible failure to report promptly to appropriate institutional officials, the institutional review board (IRB), and OHRP an unanticipated problem involving risks to subjects or others, as required by HHS regulations at 45 CFR 46.103(a) and 103(b)(5). The alleged unanticipated problem was the death of a research subject from massive capillary leak syndrome after receiving the investigational drug TXU-PAP.

Based upon its review, OHRP finds no evidence to substantiate the above allegation. In particular, OHRP acknowledges that HI's investigation revealed the following findings:

(1) Massive capillary lead is an anticipated adverse event associated with TXU-PAP therapy and the consent forms for the above research adequately described this risk.

(2) Notwithstanding that capillary leak is a potential risk of the investigational drug, no research subject died of massive capillary leak as a result of receiving TXU-PAP.

(3) HI did not fail to report promptly to appropriate institutional officials, the institutional review board (IRB), or OPRR an unanticipated problem involving risks to subjects or others, as required by HHS regulations at 45 CFR 46.103(a) and 103(b)(5).

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,

Carol J. Weil, J.D.
Compliance Oversight Coordinator
Division of Human Subject Protections

cc: Dr. Michael A. Carome, OHRP
Mr. Barry Bowman, OHRP
Dr. Jeffrey Cohen, OHRP
Mr. George Gasparis, OHRP
Dr. Greg Koski, OHRP
Dr. Melody H. Lin, OHRP
Mr. Harold Blatt, OHRP
Commissioner, FDA
Dr. David Lepay, FDA