DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

Office for Human Research Protections
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July 29, 2002

Barry S. Rabner, M.P.A.
Acting President
Lankenau Hospital-Executive Office
100 Lancaster Ave.
Wynnewood, PA 19096

RE: Human Research Subject Protections Under the Multiple Project Assurance (MPA) M-1554 and Federalwide Assurance FWA-1169

Research Project: Phase III Study of Adriamycin/Taxotere vs. Adriamycin/Cytoxan for the Adjuvant Treatment of Node Positive or High Risk Node Negative Breast Cancer
Project Number: F/N-R99-1249
Principal Investigator: Paul B. Gilman, M.D.

Dear Mr. Rabner:

The Office for Human Research Protections (OHRP) has reviewed the Main Line Hospitals (MLH) October 12, 2000 report regarding the above referenced matter. OHRP apologizes for the delay in responding to MLH's report.

Based upon its review of your report, OHRP makes the following determinations regarding the above-referenced research:

(1) In its October 24, 2001 letter to MLH, OHRP presented an allegation that the informed consent documents reviewed and approved by the institutional review board (IRB) for this protocol may have failed to adequately describe the reasonably foreseeable risks and discomforts to the subjects, as required by Department of Health and Human Services (HHS) regulations at 45 CFR 46.116 (a)(2). In specific, it was alleged that the informed consent document failed to describe adequately the risk of severe, life-threatening fluid retention secondary to Taxotere.

OHRP acknowledges that the IRB-approved informed consent document stated that Taxotere frequently causes fluid collection in the body especially in the hand, legs and sometimes around the lungs or the heart which may result in shortness of breath and may be treated with diuretics, and that some side effects may result in death. As a result, OHRP finds that the informed consent document adequately described the risk of severe, life-threatening fluid retention secondary to Taxotere.

(2) In its October 24, 2001 letter to MLH, OHRP presented an allegation that the complainant should not have been enrolled in the research project due to her overall medical condition. OHRP finds that there were no exclusion criteria for the research that the subject met, and that the inclusion and exclusion criteria appear to have been appropriate for this project.

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 commitment of your institution to the protection of human subjects. Please do not hesitate to contact me should you have any questions.

Sincerely,

Kristina C. Borror, Ph.D.
Compliance Oversight Coordinator
Division of Compliance Oversight

cc Dr. Gerald Litwack, Thomas Jefferson University
Dr. Vincent J. Cristofalo, Lankenau Institute
Dr. Albert A. Keshgegian, Chair, Lankenau Hospital IRB #1
Dr. Paul B. Gilman, Lankenau Hospital
Dr. Greg Koski, OHRP
Dr. Melody Lin, OHRP
Dr. Michael Carome, OHRP
Mr. George Gasparis, OHRP
Dr. Hal Blatt, OHRP
Mr. Barry Bowman, OHRP
Commissioner, FDA
Dr. David Lepay, FDA