



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

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April 30, 2001

Joan Mauer
Acting Chief, Clinical Trials Monitoring Branch
Cancer Therapy Evaluation Program
National Institutes of Health
EPN/Room 712
6130 Executive Blvd., MSC-7424
Bethesda, MD 20892-7424

Robert L. Comis, M.D.
Group Chair, Eastern Cooperative Oncology Group
1818 Market Street
Suite 1100
Philadelphia, PA 19103

**RE: Research Project: Evaluation of Adjuvant Therapy and Biological Parameters in
Node-Negative Operable Female Breast Cancer
Principal Investigator: Mansour EG
Study Number:E1180**

Dear Ms. Mauer and Dr. Comis:

The Office for Human Research Protections (OHRP) has reviewed Dr. Comis' report of October 22, 1999, regarding the above-referenced research conducted by the Eastern Cooperative Oncology Group (ECOG).

Based upon its review, OHRP finds that the allegation that the investigators conducting the above-referenced research failed to ensure that risks to subjects were minimized, as required by Department of Health and Human Services (HHS) regulations at 45 CFR 46.111(a)(1), was not substantiated. As a result, OHRP is closing its compliance oversight investigation of this matter and anticipates no further involvement of OHRP in this matter. Of course, OHRP must be

notified should new information be identified which might alter this determination.

At this time, OHRP provides the following guidance.

HHS regulations at 45 CFR 46.116 (a)(1) require the inclusion of the following element in informed consent documents when appropriate: the expected duration of the subject's participation. OHRP recommends that informed consent documents include information regarding the plan for long-term follow-up of subjects and performance of an autopsy after subject death.

OHRP appreciates your institution's continued commitment to the protection of human research subjects. Do not hesitate to contact me if you have any questions regarding this matter.

Sincerely,



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

cc: Dr. Greg Koski, OHRP
Dr. Melody H. Lin, OHRP
Dr. Michael A. Carome, OHRP
Dr. Jeffrey M. Cohen, OHRP
Mr. George Gasparis, OHRP
Mr. Barry Bowman, OHRP