DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

Office for Human Research Protections
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Rockville, Maryland 20852
Telephone: 240 453-8297
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February 5, 2007

Martin L. Doordan
President
Anne Arundel Medical Center
2001 Medical Parkway
Annapolis, MD 21401

RE: Human Research Subject Protections Under Federalwide Assurance (FWA) 3219
Research Project: Breast Cancer Research at the DeCesaris Cancer Institute, including "*PemFlex: Prospective Clinical Trial to Establish the Positive Predictive Value of PEM Flex PET Scanner in Detecting Additional Cancer Foci Among Women with at Least One Focus of Confirmed Primary Breast Cancer" (closed to accrual* November 21, 2005)
Principal Investigator: Dr. Lorraine Tafra

Dear Mr. Doordan:

The Office for Human Research Protections (OHRP) has reviewed Anne Arundel Medical Center's (AAMC) January 3, 2007 response to OHRP's December 22, 2006 letter concerning allegations of noncompliance with the Department of Human Services (HHS) regulations protecting human research subjects, 45 CFR part 46.

OHRP's December 22, 2006 letter found no violation of the HHS regulations by AAMC, but questioned AAMC's practice with respect to the continuing review of protocols closed to subject accrual. AAMC's response indicates that the AAMC institutional review board (IRB) conducts continuing review for all protocols until data analysis is complete and the study is terminated, in accordance with HHS regulations at 45 CFR 46.109(e). OHRP notes that HHS regulations at 45 CFR 46.110(b)(1) permit the use of expedited review procedures for specified categories of research set forth in the *Federal Register* at 63 FR 60364--60367, including continuing review of research closed to enrollment of new subjects as set forth under Category 8(a) through (c).

At this time, there is no need for further OHRP involvement in the above matter. OHRP is therefore closing this case, but requests that you notify us if you identify any new information which could alter this determination.

OHRP appreciates AAMC's continuing commitment to the protection of human research subjects.

Sincerely,

Carol J. Weil, J.D.
Compliance Oversight Coordinator
Office for Human Research Protections

cc: Dr. Joseph Moser, AAMC RIO/Human Protections Administrator
Celeste Dove, AAMC IRB Administrator
Dr. Linda Ferris, AAMC Executive Director, Oncology Initiative
Dr. Bernard Schwetz, OHRP
Dr. Melody H. Lin, OHRP
Dr. Michael Carome, OHRP
Dr. Kristina Borror, OHRP
Ms. Shirley Hicks, OHRP
Ms. Pat El-Hinnawy, OHRP
Ms. Carla Brown, OHRP
Commissioner, FDA
RADM Linda Tollefson, Assistant Commissioner, FDA