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: 240-453-8218
FAX: 240-453-6909
E-mail: paul.andreason@hhs.gov

August 21, 2006

Thomas G. McCarter, M.D.
Chief Medical Officer, Main Line Health Systems
Bryn Mawr Hospital
130 Bryn Mawr Avenue
Gerhard, 1st Floor
Bryn Mawr, PA 19010

RE: Human Research Subject Protections Under Federalwide Assurance FWA 1169

Research Project: Heart Center Research (previously described as Cardiology Department Research)

Dear Dr. McCarter:

The Office for Human Research Protections (OHRP) has reviewed the Main Line Health Systems January 27, 2006 response to OHRP's December 2, 2005 letter regarding allegations of noncompliance with Department of Health and Human Services (HHS) regulations for the protection of human research subjects (45 CFR part 46) involving the above referenced research.

Based upon its review, OHRP makes the following determination:

> Main Line Hospitals (MLH) failed to ensure that the MLH Institutional Review Board (IRB) had authority to observe or have a third party observe the consent process and the research, as required by HHS regulations at 45 CFR 46.109(e). In specific, the former Institutional Official of MLH requested an internal audit of research records for the Main Line Heart Center; however, the August 2004 scheduled audit was refused by the President of Main Line Heart Center. OHRP notes that the audit was rescheduled for September 13, 2004; however, this September 13, 2004 date was postponed indefinitely until a written policy on Routine On-Site Auditing was completed. OHRP notes that the MLH IRB must have sufficient authority to observe or have a third party observe the consent process and the research, as required by HHS regulations at 45 CFR 46.109(e). OHRP acknowledges that a written policy describing Routine On-Site Auditing by the

IRB is now in effect at MLH; however, OHRP finds this additional internal policy was not necessary for the MLH IRB to perform the internal audit that they had scheduled for August 2004.

Corrective Actions: OHRP acknowledges that MLH now ensures that the MLH IRB will not be impeded in the exercise of its authority to observe or have a third party observe the consent process and the research, as required by HHS regulations at 45 CFR 46.109(e). OHRP acknowledges that MLH committed to begin education for and the practice of Routine On-Site Auditing by the IRB in the Spring of 2006. Please clarify whether the internal audit of the Heart Center that was scheduled for August 2004 has been completed; if not, please explain why it has not occurred.

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,

Paul J. Andreason, M.D.
Compliance Oversight Coordinator
Division of Compliance Oversight

cc:

Dr. Charles L. Skutches, Director, Regulatory Affairs, Lankenau Institute for Medical Research
Dr. Albert A Keshgegian, IRB Chair, Lankenau Institute for Medical Research
Commissioner, FDA
Dr David Lepay, FDA
Dr. Bernard Schwetz, OHRP
Dr. Melody H. Lin, OHRP
Dr. Michael Carome, OHRP
Dr. Kristina Borror, OHRP
Dr. Irene Stith-Coleman, OHRP
Ms Shirley Hicks, OHRP
Ms. Patricia El-Hinnawy. OHRP
Ms. Carla Brown, OHRP