DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

Office for Human Research Protections
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October 19, 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 your letters dated January 27, 2006 and September 21, 2006. OHRP has determined that the corrective actions summarized below address the issues raised and are adequate and appropriate under Main Line Hospitals' (MLH) FWA:

> In its August 21, 2006 letter OHRP found that 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.

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. Specifically, MLH conducted the internal audit of the Heart Center that was scheduled for August 2004 during March 14-27, 2006.

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,

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
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