



Office for Human Research Protections  
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July 17, 2008

Ronald W. Swinfard, M.D.  
Chief Medical Officer  
Lehigh Valley Hospital & Health Network  
Cedar Crest & I-78  
PO Box 689  
Allentown, PA 18104

**RE: Human Research Protections Under Federalwide Assurance FWA-624**

**Research Project: A Randomized Comparison of Heart Rate Targeted vs. Fixed Dose Beta Blockade in Intermediate and High Risk Patients Undergoing Vascular Surgery**

**Principal Investigator: Martin Matsumura, M.D.**

Dear Dr. Swinfard:

Thank you for your June 11, 2008 report in response to our May 1, 2008 letter regarding research conducted under the above-referenced research project. The information provided in the June 11, 2008 report addresses the questions and concerns outlined in the May 11, 2008 letter. As a result, there should be no need for further involvement by our office in this matter. Please notify us if you identify new information which might alter this determination.

We appreciate your institution's continued commitment to the protection of human research subjects.

Sincerely,

Lisa A. Rooney, J.D.  
Compliance Oversight Coordinator

cc: Dr. Scott J. Lipkin, Director, Research Participation Protection Office, and Chair, IRB #1, Lehigh Valley Hosp & Hlth Network  
Mr. Christopher Morabito, IRB Chair, Lehigh Valley Hosp & Hlth Network IRB #2  
Dr. Martin Matsumura, Lehigh Valley Hospital

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Dr. Andrew C. von Eschenbach, Commissioner, FDA  
Dr. Joanne R. Less, FDA