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 30, 2003

Patricia A. Moore
Vice President, Clinical Services
Parma Community General Hospital
7007 Powers Boulevard
Parma, OH 44129-5495

RE: Human Research Subject Protections Under Federalwide Assurance (FWA) 00001661

Research Activity: Percutaneous Transluminal Carotid Stent Placement
Principal Investigator: Gerald Burma, M.D.

Dear Ms. Moore:

The Office for Human Research Protections (OHRP) has reviewed the Parma Community General Hospital's (PCGH) October 10, 2003 report in response to OHRP's letter of September 5, 2003 regarding the above-referenced research.

OHRP notes that PCGH has taken the following additional corrective actions:

(1) PCGH has revised its written institutional review board (IRB) procedures to better address the deficiencies noted in OHRP's letter of September 5, 2003.

(2) PCGH has provided training for its IRB to ensure that protocols undergo adequate review and that informed consent documents contain the required elements described in Department of Health and Human Services regulations at 45 CFR 46.116.

OHRP finds that these corrective actions adequately address the required actions described in OHRP's September 5, 2003 letter and are appropriate under the PCGH FWA. In addition, OHRP finds that PCGH has adequately addressed the additional concern raised in OHRP's September 5, 2003 letter. As a result of the above determinations, 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 these determinations.

At this time OHRP would like to provide the following additional guidance:

> OHRP strongly recommends that PCGH review its written IRB procedures to ensure that these documents include key operational details describing the activities of the IRB, particularly with respect to the initial review of research. OHRP again recommends that PCGH review the OHRP guidance currently located on our website at http://ohrp.osophs.dhhs.gov/humansubjects/guidance/irbgd702.htm when reviewing its written procedures.

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,

Patrick J. McNeilly, Ph.D.
Compliance Oversight Coordinator
Division of Compliance Oversight

cc: Dr. Dale H. Cowan, IRB Chair, PCGH
Ms. Darlene P. Vrotsos, IRB Administrator, PCGH
Dr. Gerald Burma, PCGH
Commissioner, FDA
Dr. David Lepay, FDA
Dr. Bernard Schwetz, OHRP
Dr. Melody H. Lin, OHRP
Dr. Michael Carome, OHRP
Dr. Kristina Borror, OHRP
Ms. Yvonne Higgins, OHRP
Ms. Shirley Hicks, OHRP
Ms. Patricia El-Hinnawy, OHRP
Ms. Melinda Hill, OHRP