DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

Office for Human Research Protections
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January 18, 2002

Ralph Snyderman, M.D.
President
Duke University Health System, Inc.
DUMC Box 3701
Durham, North Carolina 27710

John G. Currin, Jr.
Executive Vice President/Chief Operating Officer
Alamance Regional Medical Center
1240 Huffman Mill Road
Post Office Box 202
Burlington, North Carolina 27216

RE: Human Research Subject Protections Under Multiple Project Assurance (MPA) M-1106

Research Project: GUSTO IV AMI, A Phase III, Randomized, Open-Label Trial Evaluating the Efficacy and Safety of ReoPro® (Abciximab) in Combination with Reduced Dose Retavase®/Rapilysin™ (Recombinant Plasminogen Activator, Reteplase, r-PA) for the Treatment of Acute Myocardial Infarction
Principal Investigators (Alamance Regional Medical Center): Bryan Carducci, M.D., and James Strikland, M.D.

Dear Dr. Snyderman and Mr. Currin:

The Office for Human Research Protections (OHRP) has reviewed Duke University Medical Center's April 26, 2000 report and Alamance Regional Medical Center's April 14, 2000 report responding to allegations of noncompliance with Department of Health and Human Services (HHS) regulations for the protection of human research subjects (45 CFR Part 46) that were presented in OHRP's March 6, 2000 letter regarding the above-referenced research. OHRP apologizes for the delay in its response.

The allegations involved the following:

> The investigators failed to obtain and document the legally effective informed consent of the complainant prior to enrollment in the above-referenced research in accordance with all requirements of HHS regulations at 45 CFR 46.116 and 46.117.

Based upon its review of your reports, OHRP acknowledges the following:

> (1) The complainant was enrolled in the above-referenced research protocol at Alamance Regional Medical Center.
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> (2) All research interventions and interactions with the complainant under the above-referenced research protocol occurred at Alamance Regional Medical Center.
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> (3) Alamance Regional Medical Center was not part of the Duke University Health System.
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> (4) The research was not conducted or supported by HHS, nor was it conducted under an applicable OHRP-approved Assurance of Compliance at Alamance Regional Medical Center.

As a result, OHRP has determined that it does not have jurisdiction over the research activities related to the complaint and is closing its compliance oversight investigation of 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,

Michael A. Carome, M.D.
Director
Division of Compliance Oversight

cc: Dr. John M. Falletta, Chair, IRB-01, Duke University Health System
Ms. Charlotte Coley, IRB Administrator, Duke University Health System
Dr. Bryan Carducci, Alamance Regional Medical Center
Dr. James Strickland, Alamance Regional Medical Center
Commissioner, FDA
Dr. David Lepay, FDA
Dr. James F. McCormack, FDA
Dr. Greg Koski, OHRP
Dr. Melody H. Lin, OHRP
Dr. Jeffrey Cohen, OHRP

Mr. George Gasparis, OHRP
Ms. Janice Walden, OHRP
Mr. Barry Bowman, OHRP