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: 301-435-8072
FAX: 301-402-2071
E-mail:kborror@osophs.dhhs.gov

December 3, 2002

Thomas Q. Morris, M.D.
Vice President
Columbia University Health Sciences
630 West 168th St, 2-401
New York, NY 10032

RE: Human Research Subject Protections Under Multiple Project Assurance (MPA) M-1356 and Federalwide Assurance FWA-2636

Research Project: Evaluation of Intensive Pancreatic Proteolytic Enzyme Therapy with Ancillary Nutritional Support in the Treatment of Inoperable Pancreatic Adenocarcinoma
Columbia Presbyterian Medical Center (CPMC) IRB Number: 8544
Principal Investigator: John Chabot, M.D.

Dear Dr. Morris:

The Office for Human Research Protections (OHRP) has reviewed the Columbia University Health Sciences (CUHS) October 2, 2000 report regarding the above-referenced research that was submitted in response to OHRP's August 22, 2000 letter to CUHS. OHRP apologizes for the delay in responding to your report.

Based upon its review of your report, OHRP makes the following determination regarding the above-referenced research:

(1) Department of Health and Human Services (HHS) regulations at 45 CFR 46.116(a)(2) require that informed consent include a description of the reasonably foreseeable risks and discomforts of the subject's participation in the research. OHRP finds that the informed consent documents reviewed and approved by the Institutional Review Board (IRB) for this study did not list the risk of death from coffee enemas.

Corrective Action: OHRP acknowledges that, given the concerns that had been expressed, the IRB decided to require an additional statement in the consent form referring to deaths following coffee enemas and warning subjects not to exceed the amount dictated by the protocol. OHRP finds this corrective action to be adequate and appropriate under the CUHS FWA.

OHRP has the following additional concerns and questions regarding the above-referenced research:

(2) [Redacted]

(3) [Redacted]

(4) [Redacted]

(5) [Redacted]

(6) [Redacted]

(7) [Redacted]

(8) [Redacted]

Please submit to OHRP your response to the above questions and concerns no later than January 7, 2003. If upon further review of the concerns and questions, CUHS identifies instances of non-compliance with the HHS regulations for protection of human subjects, please include detailed corrective action plans to address the noncompliance. **Please note OHRP's new address.**

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,

Kristina C. Borror, Ph.D.
Compliance Oversight Coordinator
Division of Human Subject Protections

cc: Mr. Paul Papagni, CUHS IRB Administrator
Dr. John Chabot, CUHS
Dr. David LePay, FDA
Commissioner, FDA
Dr. Melody Lin, OHRP
Dr. Michael Carome, OHRP
Dr. Jeff Cohen, OHRP
Mr. George Gasparis, OHRP
Ms. Yvonne Higgins, OHRP
Mr. Barry Bowman, OHRP