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: 240 453-8218
FAX: 240 453-6909
E-mail: paul.andreason@hhs.gov

February 25, 2008

Steven Shea, M.D.
Columbia University Medical Center
Columbia University Health Sciences
Vice President & Dean's Office,
630 West 168th Street
New York, NEW YORK 10032

RE: Human Research Subject Protections Under Federalwide Assurance (FWA)-2636

Research Project:	**Gemcitabine Compared With Pancreatic Enzyme Therapy Plus Specialized Diet (Gonzalez Regimen) in Treating Patients Who Have Stage II, Stage III or Stage IV Pancreatic Cancer**
Principal Investigator:	**John Chabot, M.D.**
Project Number:	**P30-CA13696**

Dear Dr. Shea:

Thank you for your January 15, 2008 response to our letter of September 14, 2007 regarding the above-referenced research. Based on the information submitted to us, we make the following determinations regarding this research:

(1) Subject 113 was enrolled into the study more than 8 weeks after undergoing biopsy of his pancreatic tumor, which was inconsistent with the inclusion criteria stipulated in the institutional review board (IRB)-approved protocol. Department of Health and Human Services (HHS) regulations at 45 CFR 46.103(b)(4)(iii) require that the IRB review and approve all proposed changes in a research activity, during the period for which IRB approval has already been given, prior to initiation of such changes, except when necessary to eliminate apparent immediate hazards to the subjects. We determine that the enrollment of subject 113, who did not meet all eligibility criteria, represented a change in the research activity that was implemented without IRB approval.

(2) We note that Columbia University Medical Center (CUMC) found that for 40 of 62 subjects it appeared that informed consent was not documented with a signed written consent form prior to the initiation of research activities involving human subjects (e.g., receipt and analysis of identifiable private information and pathology tissue specimens, or completion of rating forms or patient diary entries), although it was documented prior to the subjects undergoing other research interventions dictated by the protocol. HHS regulations at 45 CFR 46.117(a) require that informed consent be documented by the use of a written consent form approved by the IRB and that is signed by the subject, or the subject's legally authorized representative, unless the IRB waives this requirement. We determine that the informed consent for the 40 of 62 subjects referenced by CUMC was not documented prior to the start of research activities, nor was the requirement for documentation waived by the CUMC IRB for subjects in this study.

Required Action: Please provide us with a corrective action plan that addresses the above determinations by March 21, 2008. If you need assistance in developing a corrective action plan, please feel free to contact us.

We appreciate 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.
CAPT, USPHS
Compliance Oversight Coordinator
Division of Compliance Oversight

cc: Mr. George Gasparis, Executive Director, Human Subjects Protections Program, CUMC
Dr. Andrew Wit, Chair IRB #1, CUMC
Dr. Neil Schluger, Chair IRB #3, CUMC
Dr. John Chabot, CUMC
Dr. Sherry Mills, NIH
Mr. Joseph Ellis, NIH