DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

FOR US POSTAL SERVICE DELIVERY:
Office for Human Research Protections
6100 Executive Boulevard, Suite 3B01
National Institutes of Health (MSC 7507)
Rockville, Maryland 20892-7507

FOR HAND DELIVERY OR EXPRESS MAIL:
Office for Human Research Protections
6100 Executive Boulevard, Suite 3B01
Rockville, Maryland 20852

Telephone: 301-435-5654
FAX: 301-402-0527
E-mail: sandy_leikin@nih.gov

January 25, 2001

Sister Florence Brandt
President and Chief Executive Officer
St. Francis Health System
4401 Penn Avenue
Pittsburgh, PA 15224

Michael Hansen, M.D.
St. Francis Medical Center
400-45th Street
Pittsburgh, PA 15201-1198

RE: Human Research Subject Protections Under Cooperative Project Assurance (CPA) T-3970

August 14, 2000 Food and Drug Administration (FDA) Warning Letter

Dear Sister Brandt and Dr. Hansen:

The Office for Human Research Protections (OHRP) has reviewed the November 20, 2000 and December 23, 2000 letters from St. Francis Health System (SFHS), including the draft version of the Institutional Review Board (IRB) policies and procedures, that were submitted in response to OHRP's October 11, 2000 letter.

OHRP has determined that the actions summarized in your letters appropriately address the concerns and issues raised by OHRP in its October 11, 2000 letter. As a result, OHRP has determined that there should be no need for further involvement of OHRP in the above referenced 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:

(1) According to your November 30, 2000 letter, SFHS is "actively involved" in providing an Assurance with OHRP. Please note that SFHS may not be engaged in the conduct of any Department of Health and Human Services (HHS) supported research

projects involving human subjects (including those involving data analysis only) unless (a) the research is exempt under HHS regulations at 45 CFR 46.101(b); or (b) SFHS has an applicable Assurance of Compliance approved by OHRP.

At this time it would be most appropriate for SFHS to submit to OHRP for approval a Federalwide Assurance of Protection for Human Subjects. Information and materials for filing a federalwide Assurance can be obtained from OHRP's web-site at http://ohrp.osophs.dhhs.gov/irbasur.htm. If additional OHRP guidance is needed, please contact Ms. Roslyn Edson by telephone at 301-402-7565, or by e-mail at re55q@nih.gov.

(2) OHRP notes that at its October 4, 2000 meeting the IRB voted to waive informed consent for IRB Protocol # 2010, "Heart and Lung Institute at SFMC Carotid Endarterectomy 30-day Morbidity & Mortality Results and Analysis of Predictive Factors." As you are aware, HHS regulations at 45 CFR 46.116(d) require that the IRB make and document four specific findings when approving waiver or alteration of some or all of the required elements of informed consent. OHRP strongly recommends that all required findings be fully documented in the IRB minutes, including protocol-specific information justifying each IRB finding.

OHRP appreciates the commitment of your institution to the protection of human subjects. Please do not hesitate to contact me should you have any questions.

Sincerely,

Sanford Leikin, M.D.
Compliance Oversight Coordinator
Division of Compliance Oversight

cc: Commissioner, FDA
Dr. David Lepay, FDA
Dr. James F. McCormack, FDA
Mr. Steven M. Niedelman, FDA
Dr. Jean Toth-Allen, FDA
Dr. Greg Koski, OHRP
Dr. Melody H. Lin, OHRP
Dr. Michael A. Carome, OHRP
Dr. Jeffrey M. Cohen, OHRP
Ms. Roslyn Edson, OHRP
Ms. Helen Gordon, ORHP
Mr. Barry Bowman, ORHP