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: 240-453-8297
FAX: 240-453-6909
E-mail: cweil@hhs.gov

March 19, 2009

Robert R. Simon, M.D.
Chief
Cook County Bureau of Health Services
1900 W. Polk Street, Suite 200
Chicago, IL 60612

RE: Human Research Protections Under Federalwide Assurance FWA-482 and FWA-1802

Research Project: A Phase II Trial of Doxorubicin & Docetaxel in the Neoadjuvant Treatment of Locally Advanced Breast Cancer with Correlation of Clinical, Molecular and Biological Prognostic Factors
Principal Investigators: Elizabeth Marcus, M.D. and Shalina Gupta-Burt, M.D.

Dear Dr. Simon:

Thank you for your October 1, 2008 report responding to our August 21, 2008 letter regarding the above human subject research.

Determinations regarding the above-referenced research

In our August 21, 2008 letter, we determined that the Cook County institutional review board (IRB) was not specifically informed of the investigators' intention to compensate subjects in the above research with a $20 grocery store coupon at each hospital visit, and that the IRB was therefore unable to judge whether subject consent was obtained under circumstances that minimized the possibility of coercion or undue influence in accordance with 45 CFR 46.116. We also noted that a Cook County June, 2007 policy "encouraged" investigators to discuss payments to research subjects with the IRB.

Corrective Action: Your current policy regarding payments to research subjects (dated October 1, 2008) clarifies that compensation to subjects for participation in research must be disclosed to the IRB in the protocol and must be disclosed to subjects in the informed consent process unless a waiver is obtained. This policy adequately addresses our concerns and is appropriate under your FWA.

We acknowledge your responses to the questions and concerns raised in our August 21, 2008 letter, which were provided in your October 1, 2008 letter.

At this time, there should be no need for further involvement by our office in this matter. Please notify us if you identify new information which might alter this determination.

We appreciate your institution's continued commitment to the protection of human research subjects. Please do not hesitate to contact me should you have any questions.

Sincerely,

Carol J. Weil
Division of Compliance Oversight

cc:

Ms. Mary Jane Welch, Director, Human Subjects Protection, Rush University Medical Center
Dr. Allen C. Korenblit, IRB Chair, Rush University Medical Center, IRB #1
Dr. Howard M. Kravitz, IRB Chair, Rush University Medical Center, IRB #1
Dr. Shalina Gupta-Burt, Rush University Medical Center
Ms. Lynda Brodsky, Director, Research Affairs, Cook County Bureau of Health Services
Dr. Audrey French, IRB Chair, Cook County Bureau of Health Services/Stoger Hospital
Dr. Elizabeth Marcus, Cook County Bureau of Health Services
Commissioner, FDA
Dr. Joanne Less, FDA