DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

Office for Human Research Protections
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July 19, 2005

Bonnie Phipps, CPA, CMCP
St. Joseph's Hospital Atlanta, Inc.
5665 Peachtree Dunwoody Road, NE
Atlanta, GA 30342-1764

RE: Human Research Subject Protections Under Federalwide Assurance FWA-292

Dear Ms. Phipps:

The Office for Human Research Protections (OHRP) has reviewed St. Joseph's Hospital Atlanta's (SJHA) June 16, 2005 report responding to determinations of noncompliance with Department of Health and Human Services (HHS) regulations for the protection of human research subjects (45 CFR part 46) involving the above-referenced research as outlined in OHRP's May 19, 2005 letter.

In our May 19, 2005 letter, OHRP made the following determinations, among others, regarding general human subject protections at SJHA:

> (1) HHS regulations at 45 CFR 46.110(b)(1) limit the use of expedited review procedures to specific research categories published in the Federal Register at 63 FR 60364-60367. OHRP found that the SJHA IRB inappropriately applied expedited review to research that involves minimal risk but that does not appear in the categories of research published in the Federal Register. In specific, OHRP noted that protocol #032-03, "A Study of the Effect of a Protocol Guided Rocking Chair Intervention on Delirium in Older Hospital Patients," was inappropriately reviewed in an expedited manner.
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> **Corrective Action:** OHRP acknowledges that the SJHA IRB has adopted an Expedited Reviewer Checklist that requires the reviewer to identify and document the appropriate category for expedited review. In the event the submission does not meet the criteria for an expedited review category, the submission must be presented to the convened IRB for review. OHRP notes your statement that protocol #032-03 has been terminated due to lack of response from the investigator.

(2) OHRP found that SJHA did not have written IRB procedures that adequately describe the following activities, as required by HHS regulations at 45 CFR 46.103(a) and 46.103(b)(5): the procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, any Department or Agency head, and OHRP of any unanticipated problems involving risks to subjects or others.

Corrective Action: OHRP acknowledges that the SJHA written IRB procedures have been revised to ensure that **all** unanticipated problems involving risks to subjects or others are reported to OHRP. OHRP again recommends that the written IRB procedures indicate which institutional official(s) is to receive relevant reports.

OHRP finds that the corrective actions outlined in your March 24 and June 16, 2005 reports adequately address the findings, questions, and concerns described in OHRP's May 19, 2005 letter. As a result of this determination, there should be no need for further involvement of OHRP in this matter.

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.
Director
Division of Compliance Oversight

cc: Sr. Jane Gerety, IRB Administrator/Senior VP Sponsorship/CCO
Dr. Guy Orangio, Chair, SJHA IRBs
Commissioner, FDA
Dr. David Lepay, FDA
Dr. Bernard Schwetz, OHRP
Dr. Melody H. Lin, OHRP
Dr. Michael Carome, OHRP
Dr. Irene Stith-Coleman, OHRP
Ms. Shirley Hicks, OHRP
Ms. Patricia El-Hinnawy, OHRP
Ms. Janet Fant, OHRP