DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

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November 21, 2002

Frederic Weinbaum, M.D.
Senior Vice President, Medical Affairs
The New York Hospital Medical Center of Queens
56-45 Main Street
Flushing, New York 11355

RE: Human Research Subject Protections Under Cooperative Project Assurance (CPA) T-3193 and Federalwide Assurance (FWA) 00000948

Dear Dr. Weinbaum:

The Office for Human Research Protections (OHRP) has reviewed the New York Hospital Medical Center of Queens' (NYHMC) September 28, 2000 report, as well as materials submitted on October 24, 2002, in response to OHRP's August 7, 2000 letter regarding the above-referenced research. OHRP apologizes for the delay in its response.

Based on the review of your report, OHRP finds that NHYMC has adequately addressed the allegations raised in OHRP's August 7, 2000 letter. As a result of this determination, there should be no need for further involvement of OHRP in this matter.

At this time, OHRP has the following additional guidance:

(1) The NYHMC written Institutional Review Board (IRB) procedures should be expanded to include operational details for the following procedures, in accordance with Department of Health and Human Services (HHS) regulations at 45 CFR 46.103(a) and 46.103(b)(4) and (5):

(a) The procedures which the IRB will follow for reporting its findings and actions to investigators and the institution.

(b) The procedures which the IRB will follow for determining which projects require review more often than annually.

(c) The procedures which the IRB will follow for determining which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review.

(d) The procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, any Department or Agency head, and OHRP of: (a) any unanticipated problems involving risks to subjects or others; (b) any serious or continuing noncompliance with 45 CFR Part 46 or the requirements or determinations of the IRB; and (c) any suspension or termination of IRB approval.

(2) HHS regulations at 45 CFR 46.115(a)(2) require that the minutes of IRB meetings document the vote on all IRB actions including the number of members voting for, against, and abstaining. In order to document the continued existence of a quorum, OHRP recommends that votes be recorded in the minutes using the following format: Total = 15; Vote: For-14, Opposed-0, Abstained-1 (NAME).

(3) HHS regulations at 45 CFR 46.116(d) require that the IRB make and document four findings when approving a consent procedure which does not include, or which alters, some or all of the required elements of informed consent or when waiving the requirement to obtain informed consent. OHRP recommends that when approving such a waiver for research reviewed by the convened IRB, these findings be documented in the minutes of the IRB meeting, including *protocol-specific* information justifying each IRB finding.

Similarly, where HHS regulations require specific findings on the part of the IRB, such as (a) approving a procedure which waives the requirement for obtaining a signed consent form [see 45 CFR 46.117(c)]; (b) approving research involving pregnant women, human fetuses, or neonates (see 45 CFR 46.204-207); (c) approving research involving prisoners (see 45 CFR 46.305-306); or (d) approving research involving children (see 45 CFR 46.404-407), the IRB should document such findings. OHRP recommends that for research approved by the convened IRB, all required findings be fully documented in the minutes of the IRB meeting, including *protocol-specific* information justifying each IRB finding.

For research reviewed under an expedited review procedure, these findings should be documented by the IRB Chairperson or other designated reviewer elsewhere in the IRB record.

(4) IRBs must determine which protocols require continuing review more often than annually, as appropriate to the degree of risk [see 45 CFR 46.103(b)(4) and 46.109(e)]. OHRP recommends that the minutes of IRB meetings clearly reflect these determinations regarding risk and approval period (review interval).

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,

Patrick J. McNeilly, Ph.D.
Compliance Oversight Coordinator
Division of Compliance Oversight

cc: Mr. Steven S. Mills, President and CEO, NYHMC
Ms. Karen Hultberg, IRB Administrator, NYHMC
Dr. Attallah Kappas, IRB Chair, NYHMC
Commissioner, FDA
Dr. David Lepay, FDA
Dr. Greg Koski, OHRP
Dr. Melody H. Lin, OHRP
Dr. Michael Carome, OHRP
Mr. George Gasparis, OHRP
Dr. Jeffrey Cohen, OHRP
Ms. Harold Blatt, OHRP
Mr. Barry Bowman, OHRP