DEPARTMENT OF HEALTH & HUMAN SERVICES

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August 17, 2001

Enrique Beckman, M.D., Ph.D.
Chairman of the Board of Directors
Michael Reese Hospital
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William A. Clark, Ph.D.
Executive Director
Research and Education Foundation and Research Director
Michael Reese Hospital IRB
2816 S. Ellis Ave., Room. 753
Chicago, IL 60616

RE: Human Research Subject Protections Under the Multiple Project Assurance (MPA) M-1014

Dear Dr. Beckman and Dr. Clark:

The Office for Human Research Protections (OHRP) has reviewed the Michael Reese Hospital's (MRH) report of July 13, 2001. Based upon its review, OHRP has determined that MRH has adequately addressed the concerns raised in OHRP's letter of June 1, 2001. In particular, OHRP notes the following corrective actions taken by MRH:

(1) MRH has conducted an audit of all ongoing research and appropriately suspended research which was not properly reviewed by the MRH Institutional Review Board (IRB).

(2) The MRH has assured OHRP that it will review protocol amendments as required by Department of Health and Human Services (HHS) regulations.

(3) MRH has provided adequate written IRB policies and procedures and has indicated that the MRH IRB has devoted a number of sessions to further updating these policies and procedures in light of the guidance provided in OHRP's June 1, 2001 letter.

(4) MRH has implemented a satisfactory educational program for investigators, staff and IRB members on an ongoing basis about the ethical principles and regulatory requirements for the protection of human subjects.

As a result of the above determination, OHRP anticipates no further involvement in the above matter. Of course, OHRP must be notified should new information be identified which might alter this determination.

Per your request under item 8 of your letter, OHRP would like to provide the following additional guidance:

(5) 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 strongly recommends that votes be recorded in the minutes using the following format: Total = 15; Vote: For-14, Opposed-0, Abstained-1 (NAME). Additionally, IRB minutes must be in sufficient detail to show the basis for requiring changes in or disapproving research, as well as a summary of the discussion of controverted issues and their resolution.

(6) Where HHS regulations require specific findings on the part of the IRB, such as (a) approving a procedure which alters or waives the requirements for informed consent [see 45 CFR 46.116(d)]; (b) approving a procedure which waives the requirement for obtaining a signed consent form [see 45 CFR 46.117(c)]; (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 strongly recommends that all required findings be fully documented in the IRB minutes, including protocol-specific information justifying each IRB finding.

(7) 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).

(8) The MRH Administrative Policy for Research and Development Studies on Human Subjects (section E.6, page 7) states, "Any suspension or termination of approval shall include a statement of the IRB's reason for such action. The Chairperson shall promptly notify the department head, the responsible institutional official and, where applicable, the sponsoring agency of such action." HHS regulations at 45 CFR 46.103(b)(5) require that such actions also be reported to OHRP. OHRP recommends that this be incorporated into the MRH policy.

(9) The MRH Administrative Policy for Research and Development Studies on Human Subjects (section E.7, page 7) states, "Reports of subjects who sustain unanticipated or serious adverse events shall be promptly made by the investigator to the IRB Chairperson." OHRP notes that HHS regulations at 45 CFR 46.103(b)(5) requires the reporting of unanticipated problems involving risks to subjects or others. OHRP wishes to emphasize that unanticipated problems may involve situations other than adverse

events. OHRP recommends that MRH update its policy to reflect the this distinction

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

Sincerely,

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

cc: Dr. Thomas Glonek, IRB Chair, Michael Reese Hospital
Ms. Joyce Washington, Michael Reese Hospital
Ms. Joan Mauer, CTEP, NCI
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