



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

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July 17, 2000

Mr. John M. Allen
Assistant Vice President for Scientific Affairs
Office of Scientific Affairs
State University of New York
Health Science Center at Brooklyn
450 Clarkson Avenue, Box 129
Brooklyn, NY 11203-2098

RE: Multiple Project Assurance (MPA) M-1073

Dear Mr. Allen:

The Office for Human Research Protections (OHRP), formerly the Office for Protection from Research Risks, has reviewed your December 17, 1999 letter.

Based on its review of your report, OHRP makes the following determinations regarding the protection of human subjects at the State University of New York Health Science Center at Brooklyn:

(1) Department of Health and Human Services (HHS) regulations at 45 CFR 46.108 require that, except when an expedited review procedure is used, the IRB review proposed research at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. OHRP finds that the February 26, 1999 Institutional Review Board (IRB) Emergency Committee meeting was convened without a quorum. As such any actions taken at the above referenced meeting should be considered invalid.

Required Action: Any research approved at the meeting that has not undergone subsequent review at an appropriately convened IRB meeting must be suspended until such IRB review occurs. By August 18, 2000, please provide OHRP with a list of all suspended protocols, and State University of New York at Brooklyn (SUNY-Brooklyn) Health Science Center's plan to review such research.

(2) HHS regulations at 45 CFR. 46.116(d) require that the IRB make and document four specific findings when approving a waiver of the requirements to obtain informed consent. OHRP finds that the IRB failed to make and document these required findings when it approved a waiver of the requirement to obtain informed consent for protocol #95-113.

Required Action: OHRP acknowledges that the IRB has implemented a procedure to document such findings in the minutes of IRB meetings. Nevertheless, the IRB should re-review #95-113, including project specific information justifying each finding. Please provide the documentation of these IRB findings for protocol #95-113 by August 18, 2000.

In addition, OHRP has the following additional questions and concerns:

(3) Regarding the vote taken on November 18, 1998 by the IRB to allow future expedited annual review of Protocol #98-144, the regulations do provide for such an action. However, as research may undergo changes that may result in additional risks, a determination as to whether the expedited procedure can still be applied must be made at the time of each subsequent review. Whenever the research involves more than minimal risk, the research must be reviewed by the convened IRB.

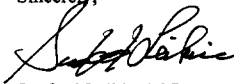
(4) Your response concerning Protocol #95-113 states that, because the research presents no risk to the subjects, "the study clearly meets the criteria mandated in Section 46.406." However, HHS regulations at 45 CFR 46.406 applies to research involving greater than minimal risk. Please explain this discrepancy.

(5) OHRP's letter of September 24, 1999 requested that you provide copies of all IRB meetings from March, 1999 to the time of your response. No copies were forthcoming with your response. At this time OHRP again requests that you provide copies of minutes of all IRB meetings convened from March, 1999 to the present.

Please forward your response to the above findings, questions, and concerns so that OHRP receives it no later than August 18, 2000.

OPRR 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,



Sanford Leikin, M.D.
Compliance Oversight Coordinator
Division of Human Subject Protections

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State University of New York at Brooklyn Health Science Center

July 17, 2000

cc: Dr. Melody H. Lin, OHRP
Dr. J. Thomas Puglisi, OHRP
Dr. Michael Carome, OHRP
Ms. Michele Russell-Einhorn, OHRP
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