DEPARTMENT OF HEALTH & HUMAN SERVICES

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February 28, 2001

Keith McLaughlin
Chief Executive Officer
Raritan Bay Medical Center
530 Brunswick Avenue
Perth Amboy, NJ 08861

RE: Human Research Subject Protections Under Cooperative Project Assurance (CPA) T-4548
Research Projects: DAIDS Community Programs for Clinical Research on AIDS (CPCRA)

Dear Mr. McLaughlin:

The Office for Human Research Protections (OHRP) has reviewed your January 12, 2001 report concerning research involving prisoners as subjects that was conducted by Raritan Bay Medical Center (RBMC).

Based upon its review, OHRP makes the following determinations:

(1) OHRP finds that the following corrective actions taken by RBMC adequately address the findings made by OHRP in its November 27, 2000 letter:

(a) RBMC has notified all its investigators that research may not be conducted on prisoners, and that in the event RBMC decides to revise its policy to permit involvement of prisoners in Department of Health and Human Services (HHS)-supported research, RBMC will revise its Institutional Review Board (IRB) policies and procedures in accordance with HHS regulations at 45 CFR Part 46 Subpart C.

(b) RBMC has revised its draft Policy and Procedure Manual to include quorum requirements stipulated by HHS regulations at 45 CFR Part 46.108. Furthermore, open projects that were approved at meetings at which a quorum was not present will be re-reviewed by the RBMC IRB.

(c) The RBMC IRB has abolished the practice of granting a grace period for continuing review.

(d) The RMBC Policy and Procedure Manual is being rewritten to address the concerns in OHRP's November 27, 2000 letter.

(2) OHRP finds that RBMC has adequately responded to the additional major concerns and questions raised by OHRP in its November 27, 2000 letter.

As a result of the above determinations, OHRP has closed its compliance oversight evaluation of the above-referenced research and anticipates no further OHRP involvement in this matter. Of course, OHRP must be notified should new information be identified which might alter this determination.

At this time, OHRP provides the following additional guidance.

(3) OHRP recommends that RBMC expand its operational procedures in the Policy and Procedure Manual for the IRB. For example, OHRP suggests that the Manual include more details regarding the actual process of review (such as the use of primary and secondary reviewers and which member leads the discussion of a particular protocol), and more details regarding the procedures by which the IRB determines which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review.

(4) The draft revised RMBC Policy and Procedure Manual for the IRB corrects the quorum requirements for the IRB. However, the manual notes that "the majority must include at least one member not associated with the Raritan Bay Medical Center." The HHS regulations at 45 CF 46.108(b) state that convened meetings must include "at least one member whose primary concerns are in nonscientific areas." OHRP acknowledges that the RBMC IRB's current lay members are all unaffiliated with RBMC. However, if this constitution should change in the future, a non-scientific member needs to be present.

(5) The draft revised manual states that non-English consent forms must be approved by the IRB. OHRP notes that it may be helpful to require or obtain a back-translation of such non-English forms to ensure accuracy of translation.

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,

Kristina C. Borror, Ph.D.
Compliance Oversight Coordinator
Division of Compliance Oversight

cc: Dr. Sidney Kress, Chair, RBMC IRB
Dr. Nina Regevik, RBMC
Ms. Judith Brooks, DAIDS/NIAID
Commissioner, FDA
Dr. David Lepay, FDA
Dr. James F. McCormack, FDA
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