



FOR US POSTAL SERVICE DELIVERY:

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March 28, 2001

Mr. Michael J. Sullivan
Director
Department of Veterans Affairs Medical Center
University and Woodland Avenues
Philadelphia, PA 19104

RE: Human Research Subject Protections Under Multiple Project Assurance (MPA) M-1528

Research Projects: Cardiology Clinic Research Activities
Principal Investigator: Dr. W. Bruce Dunkman

Dear Mr. Sullivan:

The Office for Human Research Protections (OHRP) has reviewed the Philadelphia Veterans Affairs Medical Center (PVAMC) report dated March 19, 2001 regarding the above referenced research and PVAMC's system for protecting human subjects.

OHRP has determined that the corrective actions summarized below appropriately address the findings made in OHRP's February 15, 2001 letter:

(1) OHRP found that PVAMC failed to report the suspension of the BEST and PRAISE-2 studies to OHRP, as required by Department of Health and Human Services (HHS) regulations at 45 CFR 46.103(a) and 103(b)(5).

Corrective Action: PVAMC has implemented procedures to ensure prompt reporting to the IRB, appropriate institutional officials, and OHRP of (i) any unanticipated problems involving risks to subjects or others; (ii) any serious or continuing noncompliance with the requirements of 45 CFR Part 46 or the requirements or determinations of the institutional review board (IRB); and (iii) any suspension of termination of IRB approval.

(2) OHRP found that the PVAMC IRB failed to meet the quorum requirements stipulated by HHS regulations at 45 CFR 46.108 for two meetings in 1992 and one meeting in 1997.

Corrective Action: PVAMC has implemented procedures to ensure that no actions are taken by the IRB in the absence of a convened quorum of the IRB. Furthermore, OHRP acknowledges that PVAMC has conducted a review of all studies previously approved at meetings lacking a quorum and the PVAMC IRB has appropriately re-reviewed any studies that were still active.

(3) OHRP found instances where an IRB member with a conflicting interest participated in the initial and continuing review of protocols for which that member had a conflicting interest, in contravention of the requirements of HHS regulations at 45 CFR 46.107(e).

Corrective Action: The PVAMC IRB has implemented procedures to ensure that any member with a conflicting interest related to a research protocol will not participate in review of and action on the protocol.

(4) OHRP found that a research project was not undergoing continuing review by the IRB at least annually, as required by HHS regulations at 45 CFR 46.109(e).

Corrective Action: The PVAMC IRB has implemented procedures to ensure that all research projects undergo continuing review at least annually.

Furthermore, OHRP finds that the PVAMC has developed an adequate plan for ensuring that all IRB members, staff, and researchers are appropriately educated, on an ongoing basis, about the ethical principles and regulatory requirements for the protection of human subjects.

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

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: Dr. Ronald P. Daniele, PVAMC
Ms. Patricia Wallace, PVAMC
Dr. Dr. Peter M. Jucovy, Chairperson, IRB, PVAMC
Dr. W. Bruce Dunkman, Cardiology Clinic, PVAMC
Dr. John H. Mather, Veterans Health Administration, Department of Veterans Affairs

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Commissioner, FDA

Dr. David Lepay, FDA

Dr. James F. McCormack, FDA

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Mr. Barry Bowman, OHRP