DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

FOR US POSTAL SERVICE DELIVERY:
Office for Human Research Protections
6100 Executive Boulevard, Suite 3B01
National Institutes of Health (MSC 7507)
Rockville, Maryland 20892-7507

FOR HAND DELIVERY OR EXPRESS MAIL:
Office for Human Research Protections
6100 Executive Boulevard, Suite 3B01
Rockville, Maryland 20852

Telephone: 301-435-0668
FAX: 301-402-2071
E-mail: mcneillp@od.nih.gov

March 29, 2001

Michael D. Rich
Executive Vice President
RAND
1700 Main Street
P.O. Box 2138
Santa Monica, CA 90407-2138

Tora K. Bikson, Ph.D.
Chair, Human Subjects Protection Committee
RAND
1700 Main Street
P.O. Box 2138
Santa Monica, CA 90407-2138

RE: Human Subjects Protections under Multiple Project Assurance (MPA) M-1031

Project Title: HIV Cost and Services Utilization Study
HHS Project #: U01-HS08578
Principal Investigator: Martin Shapiro, M.D.

Dear Mr. Rich and Dr. Bikson:

The Office for Human Research Protections (OHRP) has reviewed your February 28, 2001 report regarding the above referenced research protocol and RAND's system for protection of human subjects.

OHRP has determined that RAND has implemented all required and recommended actions stipulated in OHRP's November 27, 2000 letter. In particular OHRP notes the following:

(1) RAND has appointed two prisoner representatives to its Institutional Review Board (IRB) for review of research which involves prisoners.

(2) RAND has implemented a plan to document the required findings for:

(a) Approval of a waiver or modification of the standard informed consent requirements.

(b) Approval of a waiver of the requirement for obtaining a signed written consent form.

(c) Approval of research involving prisoners.

(d) Approval of research involving children.

(3) RAND has developed written IRB Policies and Procedures that adequately describe each of the activities required by HHS regulations at 45 CFR 46.103(b)(4) and (5).

Additionally, OHRP acknowledges RAND's efforts in providing information for investigators related to IRB procedures via its intranet and the interactive roll of its IRB staff.

As a result of the above determination, 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.

At this time OHRP would like to provide the following additional guidance:

(4) OHRP acknowledges the statement made in your report that RAND engages in behavioral research and does not conduct clinical trials involving biomedical experimentation. OHRP would like to point out that HHS regulations at 45 CFR 46.102(d) define research as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. For the purposes of complying with the regulations, no distinction is made between behavioral and biomedical research.

(5) OHRP strongly recommends that the information relating to (a) the procedures for determining which projects require review more often than annually, and (b) procedures for reporting of unanticipated problems involving risks to subjects or others, described in RAND's February 28, 2001 report, be incorporated into its written IRB policies and procedures.

(6) Regarding RAND's use of e-mail for the recording of votes on an IRB motion, OHRP would like to point out that HHS regulations at 45 CFR Part 46 make no provisions, outside of an expedited review process, for the conduct of IRB business other than at a convened IRB meetings, even under the limited circumstances described by RAND.

OHRP appreciates the continued commitment of your institution to the protection of human research subjects.

Sincerely,

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

cc: Dr. James A. Thomson, RAND
Commissioner, FDA
Dr. David Lepay, FDA
Dr. James F. McCormack, FDA
Dr. Greg. Koski, OHRP
Dr. Melody H. Lin, OHRP
Dr. Michael A. Carome, OHRP
Ms. Freda Yoder, OHRP
Dr. Kamal Mittal, OHRP
Dr. Jeffrey M. Cohen, OHRP
Mr. Barry Bowman, OHRP