DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

Office for Human Research Protections
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October 25, 2001

Michael M. Gottesman, M.D.
Deputy Director for Intramural Research
National Institutes of Health
Building 1, Room 114
Bethesda, MD 20892

RE: Human Research Subject Protections Under Multiple Project Assurance (MPA) M-1000

Research Projects:	**Mechanisms of Drug Disposition in Hair**
Intramural Institute:	**National Institute on Drug Abuse (NIDA)**
Principal Investigator:	**Dr. Edward J. Cone**

Dear Dr. Gottesman:

The Office for Human Research Protections (OHRP) has reviewed your report dated March 23, 2001 in response to OHRP's letter of January 24, 2001. Based upon its review of your report, as well as a meeting with National Institutes of Health officials on May 1, 2001, OHRP finds that the following corrective actions and clarifications provided by the National Institute on Drug Abuse (NIDA) adequately address the findings and required actions stipulated by OHRP in its January 24, 2001 letter:

(1) The NIDA Institutional Review Board (IRB) has required the investigator conducting the above-referenced research to include a statement in the informed consent document to indicate that if the subject leaves the study early, agents administered during the study may produce a positive drug test which may have adverse consequences for the subject.

(2) NIDA has revised its policy on remuneration of subjects involved in research. The new policy adequately addresses the concerns raised in OHRP's January 24, 2001 letter regarding the possibility of coercion or undue influence resulting from forfeiture of a significant portion of the subject's remuneration under certain circumstances.

(3) NIDA has provided OHRP with a copy of its policy for the administration of cocaine to human participants which addresses OHRP's concerns regarding the dosing of subcutaneous cocaine.

(4) The NIDA IRB has agreed with OHRP's guidance that substantive modifications or clarifications to research protocols, requested by the IRB, require approval by the fully convened IRB.

(5) NIDA has clarified its position on the recruitment of subjects and its efforts in recruiting subjects from a diverse group of neighborhoods, in order to promote equitable selection of subjects.

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.

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. Ruth Kirschstein, Acting Director, NIH
Dr. Alan I. Leshner, NIDA
Dr. David Gorelick, IRB Chairperson, NIDA
Dr. Alan L. Sandler, OHSR, NIH
Commissioner, FDA
Dr. David Lepay, FDA
Dr. James F. McCormack, FDA
Dr. Greg Koski, OHRP
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Dr. Jeffrey M. Cohen, OHRP
Mr. George Gasparis, OHRP
Dr. Harold Blatt, OHRP
Mr. Barry Bowman, OHRP