



Office for Human Research Protections
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July 16, 2002

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

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

Dear Dr. Gottesman:

The Office for Human Research Protections (OHRP) has reviewed your June 20 and March 22, 2002 letters responding to findings made by OHRP as a result of its February 20-21, 2002 not-for-cause compliance oversight site visit to the National Institute on Alcohol Abuse and Alcoholism (NIAAA).

OHRP has determined that the corrective actions taken by NIAAA adequately address OHRP's findings and required and recommended actions that were presented in OHRP's March 12, 2002 letter. As a result, 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,

Carol J. Weil, J.D.
Compliance Oversight Coordinator
Division of Human Subject Protections

NIAAA – Dr. Michael M. Gottesman

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cc: Dr. Alan L. Sandler, OHSR/NIH
Dr. Ted George, NIAAA
Dr. David Goldman, Chair, IRB, NIAAA
Dr. Greg Koski, OHRP
Dr. Melody Lin, OHRP
Dr. Michael Carome, OHRP
Dr. George Gasparis, OHRP
Mr. Harold Blatt, OHRP
Mr. Bob Meyer, OHRP
Dr. Leslie Ball, OHRP
Dr. Jeffrey Cohen, OHRP
Mr. Barry Bowman, OHRP
Commissioner, FDA
Dr. David Lepad, FDA