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 30, 2002

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 Project: Population Differences in the Insulin Sensitivity, Resting Energy Expenditure, and Body Composition of Overweight Children and Children of Overweight Parents
Protocol Number: 96-CH-0101
Principal Investigator: Jack A. Yanovski, M.D., Ph.D.

Dear Dr. Gottesman:

The Office for Human Research Protections (OHRP) has completed its review of the materials provided with your February 7, 2001 letter that was submitted in response to OHRP's January 17, 2001 letter regarding the above-referenced research.

Based upon its review, OHRP offers the following guidance:

OHRP noted significant variation amongst the various National Institutes of Health (NIH) institutional review boards (IRBs) with respect to the documentation of the findings required by Department of Health and Human Services (HHS) regulations at 45 CFR part 46, subpart D.

Where HHS regulations require specific findings on the part of the IRB, such as (a) approving a procedure which waives the requirement for obtaining a signed consent form [see 45 CFR 46.117(c)]; (b) approving research involving pregnant women, human fetuses, or

neonates (see 45 CFR 46.204-207); (c) approving research involving prisoners (see 45 CFR 46.305-306); or (d) approving research involving children (see 45 CFR 46.404-407), the IRB should document such findings. OHRP recommends that for research approved by the convened IRB, all required findings be fully documented in the minutes of the IRB meeting, including *protocol-specific* information justifying each IRB finding. For research reviewed under an expedited review procedure, these findings should be documented by the IRB Chairperson or other designated reviewer elsewhere in the IRB record

OHRP is aware that NIH has taken steps to ensure that the findings required by HHS regulations are consistently documented by the NIH IRBs.

OHRP has determined that there should be no need for further involvement of OHRP in this matter. As a result, OHRP is closing its compliance oversight evaluation related to the above- referenced research. 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,

Michael A. Carome, M.D.
Director, Division of Compliance Oversight

cc: Dr. Elias Zerhouni, Director, NIH
Dr. Duane Alexander, Director, NICHD
Dr. Alan Sandler, Director, OHSR, NIH
Dr. Gilman Grave, Chair, IRB, NICHD, NIH
Dr. Jack Yanovski, NICHD, NIH
Commissioner, FDA
Dr. David Lepay, FDA
Dr. Greg Koski, OHRP
Dr. Melody Lin, OHRP
Mr. George Gasparis, OHRP
Dr. Jeffrey M. Cohen, OHRP
Mr. Barry Bowman, OHRP