DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

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January 17, 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 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 received your December 8, 2000 report regarding the above referenced research that was submitted in response to OHRP's November 3, 2000 letter.

We would like to thank the National Institute of Child Health and Human Development (NICHD) Institutional Review Board (IRB) for the careful consideration given to the issues raised by OHRP in reference to this study. Clearly, these are complex issues, and thoughtful dialogue will help to achieve greater clarity. OHRP is carefully reviewing and considering the viewpoints expressed by the NICHD IRB at its November 15, 2000 meeting. A formal response will follow once OHRP has completed this review.

In the meantime, OHRP hereby approves your verbal request to allow the yearly health evaluations with nutrition assessment, medical history, physical examination and psychological questionnaires to resume in subjects who have already enrolled in above referenced research. However, enrollment of new subjects in the research and the performance of all other

interventions in currently enrolled subjects, until further notice from OHRP, remain suspended pending resolution of the outstanding issues.

At this time, OHRP requests that you provide the complete IRB records for each of the following protocols: OH96-CH-N022, OH98-CH-N002, OH98-CH-N055, OH00-CH-N003, 93-N-0191, 89-M-0006, 93-M-0122, 97-H-0099, OH91-DK-0165, 87-I-0163, 90-I-0120, OH94-I-N046, 98-I-0104. For each of these protocols, please provide the following:

(1) The IRB-approved research protocol (all versions since the time of initial IRB approval).

(2) The IRB-approved informed consent documents (all versions since the time of initial IRB approval).

(3) The relevant IRB minutes, including initial review, continuing review, review of changes to the research or the informed consent document, and review of any adverse events or unanticipated problems.

(4) A summary of the IRB's determinations with respect to the requirements of Department of Health and Human Services regulations at 45 CFR 46.404-406 and the justification for these determinations

(5) The IRB's correspondence with the investigators.

(6) All continuing review reports and protocol amendments.

(7) A chronological summary of the dates of the IRB's actions.

(8) A copy of any publications or presentations which were derived from the research.

(9) Any other pertinent information.

Please submit the above documents to OHRP no later than February 7, 2001.

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

Sincerely,

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

cc: Dr. Ruth Kirschstein, Acting 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
Dr. Greg Koski, OHRP
Dr. Melody Lin, OHRP
Mr. George Gasparis, OHRP
Dr. Jeffrey M. Cohen, OHRP