DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

Office for Human Research Protections
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January 12, 2004

Thomas J. Rosol, D.V.M., Ph.D.
Interim Vice President for Research
The Ohio State University
Office of Research
208 Bricker Hall
190 North Oval Mall
Columbus, OH 43210-1321

RE: Human Research Subject Protections Under Multiple Project Assurance (MPA) M-1238

Research Publication: **Charcot-Marie Tooth Neuropathy Gene Mutation and Their Role in Pathogenesis**
Principal Investigator: **Zarife Sahenk, M.D.**

Dear Dr. Rosol:

The Office for Human Research Protections (OHRP) has reviewed the Ohio State University's (OSU) October 23, 2003 report in response to OHRP's letter of September 29, 2003 regarding the above-referenced research.

OHRP notes that OSU has taken the following corrective actions:

(1) OSU has terminated the investigator's research involving human subjects.

(2) OSU has disqualified the investigator from serving as principal investigator on research protocols involving human subjects for a period of two years.

(3) OSU has required that, to have the investigator's privileges to conduct research involving human subjects reinstated, the investigator must (i) undergo face-to-face good research practices training; (ii) have ongoing departmental supervision; (iii) develop a

revised recordkeeping system; and (iv) be subject to ongoing auditing of any future human subjects research.

(4) OSU is in the process of recruiting a full-time auditor within the Office for Responsible Research Practices (ORRP) to help prevent future occurrences of noncompliance. In addition, the ORRP will increase its educational efforts for investigators to reinforce the requirement for prospective institutional review board (IRB) review and approval for all changes in a research activity.

(5) OSU has revised its Human Subjects Violation Policy to fully comply with the requirements for reporting any suspension or termination of IRB approval of human subjects research.

OHRP finds that these corrective actions adequately address the required actions described in OHRP's September 29, 2003 letter and are appropriate under the OSU MPA. As a result of this 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. Judith Neidig, Director, Office of Responsible Research Practices, OSU
Dr. Arthur F. Hefti, Chair, Biomedical Sciences IRB, OSU
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