DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

Office for Human Research Protections
The Tower Building
1101 Wootton Parkway, Suite 200
Rockville, Maryland 20852

Telephone: 301-435-0668
FAX: 301-402-2071
E-mail: pmcneilly@osophs.dhhs.gov

September 15, 2003

Fawwaz T. Ulaby, Ph.D.
Vice President for Research
University of Michigan
4080 Fleming Building
503 Thompson Street
Ann Arbor, MI 48109-1340

RE: Human Research Subject Protections Under Federalwide Assurance (FWA) FWA 00004969

Research Activity: Albers, J.W. *et al.* Absence of Polyneuropathy Among Workers Previously Diagnosed with Solvent-Induced Toxic Encephalopathy, *Journal of Occupational and Environmental Medicine* 41:500-509;1999.

Albers, J.W. *et al.* Neurologic Evaluation of Workers Previously Diagnosed with Solvent-Induced Toxic Encephalopathy, *Journal of Occupational and Environmental Medicine* 42:410-423;2000.

Principal Investigator: Dr. James Albers
Protocol Number: IRBMED 1997-311

Dear Dr. Ulaby:

The Office for Human Research Protections (OHRP) has reviewed the University of Michigan's (UM) March 31, 2003 and August 28, 2003 reports in response to OHRP's letters of February 12, 2003 and July 15, 2003 regarding the above-referenced research activity.

After reviewing UM's reports, OHRP makes the following determinations regarding the above-referenced research:

(1) OHRP notes that UM has taken the following corrective actions:

(a) UM has reaffirmed its commitment to ensure that any determinations necessary for granting a waiver of informed consent are documented in the minutes of the UM institutional review board (IRB) meetings.

(b) In an effort to enhance its system for protection of human subjects, UM has implemented the following changes:

(i) Established a University-wide Human Research Coordinating Council

(ii) Enhanced the capacity and capabilities of its IRBs.

(iii) Required basic education and certification for individuals involved in human subjects research.

(iv) Established a new Office of Research Compliance Review.

(v) Developed a comprehensive electronic administration and documents processing system.

(vi) Provided enhanced clinical research support.

OHRP finds these corrective actions adequately address the determination in OHRP's February 12, 2003 letter and are appropriate under the UM FWA.

(2) OHRP finds that UM has adequately addressed the additional concerns raised in OHRP's February 12, 2003 letter.

As a result of the above determinations, 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 Nowack, Assistant Vice President for Research, UM
Dr. James Albers, UM
Dr. Robert Cody, Chair, IRB #1 and #6, UM
Dr. Charles Kowalski, Chair, IRB #2, UM
Mr. John O'Shea, Chair, IRB #3, UM
Dr. Gerald Gardner, Chair, IRB #4, UM
Dr. Suzanne Selig, Chair, IRB #5, UM
Dr. Vernon Sondak, Chair, IRB #7 and #8, UM
Dr. Bernard Schwetz, OHRP
Dr. Melody Lin, OHRP
Dr. Michael A. Carome, OHRP
Dr. Kristina Borror, OHRP
Ms. Yvonne Higgins, OHRP
Ms. Shirley Hicks, OHRP
Ms. Patricia El-Hinnawy, OHRP
Ms. Melinda Hill, OHRP