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

February 12, 2003

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

RE: Human Research Subject Protections Under Multiple Project Assurance (MPA) M-1184

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

Dear Dr. Ulaby:

The Office for Human Research Protections (OHRP) has reviewed the University of Michigan's (UM) October 19, 2001 report in response to OHRP's letter of August 2, 2001 regarding the above-referenced research activity.

OHRP notes the following:

(1) The above-referenced research activity was submitted to the UM institutional review board (IRB) as three separate studies (IRBMED 1997-309, IRBMED 1997-310, and IRBMED

1997-311), each involving retrospective review of medical records and recording of the research data without direct or indirect identifiers. The exception to this is that IRBMED 1997-311 also involved the prospective use of control subjects. The UM IRB reviewed and approved each of these studies at a convened meeting of the IRB.

(2) The UM IRB approved a waiver of the requirement for informed consent for all research involving retrospective review of medical records for each of the studies.

Based on its review of your October 19, 2001 report, OHRP makes the following determination:

(1) Department of Health and Human Services (HHS) regulations at 45 CFR 46.116(d) require that the IRB find and document four specific criteria when approving waiver or alteration of some or all of the required elements of informed consent. OHRP finds that the UM IRB failed to document the specific criteria for waiver of informed consent for the above-referenced research.

Required Action: By March 31, 2003, UM must submit to OHRP a satisfactory corrective action plan to address the above finding.

At this time OHRP has the following additional comments and concerns:

(2) [Redacted]

(3) [Redacted]

(4) [Redacted]

Please forward your response to the above required action and additional concerns so that OHRP receives it no later than March 31, 2003.

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. Vernon Sondak, Co-Chair, IRB-MED, UM
Dr. Robert Cody, Co-Chair, IRB-MED, UM
Dr. Charles Kowalski, Chair, IRB-Health, UM
Mr. John O'Shea, Co-Chair, IRB-BehavSci, UM
Ms. Daphna Oysterman, Co-Chair, IRB-BehavSci, UM
Dr. Melody Lin, OHRP
Dr. Michael A. Carome, OHRP
Dr. Kristina Borror, OHRP
Mr. George Gasparis, OHRP
Ms. Shirley Hicks, OHRP
Dr. Harold Blatt, OHRP
Mr. Barry Bowman, OHRP