DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

Office for Human Research Protections
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November 27, 2002

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

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

Research Activity: Department of Radiology Research Activities

Dear Dr. Ulaby:

The Office for Human Research Protections (OHRP) has reviewed the University of Michigan's (UM) October 15, 2002 and November 15, 2002 reports submitted in response to OHRP's September 16, 2002 letter regarding the above-referenced research activities. OHRP acknowledges the following corrective action taken by UM:

(1) UM has submitted a revised Department of Radiology policy relating to human subject research.

(2) UM has implemented an appropriate plan to ensure that researchers within the Department of Radiology properly obtain and document legally effective informed consent of human subjects enrolled in research. The plan includes the following components:

(a) The designation of two research compliance staff.

(b) Implementation of an education and monitoring plan which includes a requirement that all faculty complete a training program on the protection of human subjects.

(c) Creation of a secure central repository for copies of informed consent documents within the Department of Radiology.

(d) A requirement to submit a 6-month follow-up report on the outcomes of the corrective action plan to the Office of the Vice President for Research.

OHRP finds that the above corrective actions adequately address the required actions stipulated in OHRP's September 16, 2002 letter. In addition, OHRP finds that UM has adequately addressed the additional questions and concerns raised in its September 16, 2002 letter. As a result of the above determinations, there should be no need for further involvement of OHRP in this matter.

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: Ms. Judith A. Nowack, Assistant Vice President for Research, UM
Dr. Vernon Sondak, Chair IRB #1, UM
Dr. Robert J. Cody, Chair IRB #2, UM
Commissioner, FDA
Dr. David Lepay, FDA
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Dr. Melody H. Lin, OHRP
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