DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

Office for Human Research Protections
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August 26, 2002

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

RE: Human Research Subject Protections Under Multiple Project Assurance (MPA) M-1184
Research Project: HPA Axis Dysregulation in Fibromyalgia
Principal Investigator: Dr. Leslie Crofford

Dear Dr. Ulaby:

The Office for Human Research Protections (OHRP), formerly the Office for Protection from Research Risks (OPRR), has reviewed your August 8, 2000 report responding to OPRR's request that the University of Michigan (UM) evaluate allegations of noncompliance with Department of Health and Human Services (HHS) regulations for the protection of human research subjects (45 CFR Part 46) involving the above-referenced research. OHRP apologizes for the delay in its review.

The allegations involve the following:

(1) Failure of the investigators to ensure that risks to subjects were minimized as required by HHS regulations at 45 CFR 46.111(a)(1). In specific, the investigators failed to provide appropriate medical evaluation and treatment for adverse events that occurred following a research intervention.

(2) A subject suffered serious unanticipated problems involving risks to subjects that were not promptly reported to the Institutional Review Board (IRB), appropriate institutional officials,

and OPRR as required by HHS regulations at 45 CFR 46.103(a) and 46.103(b)(5).

(3) UM failed to provide medical treatment for the serious adverse events that resulted from a research procedure, despite statements in the informed consent document that such care would be provided.

Based upon UM's report, OHRP finds no evidence substantiating the above allegations. OHRP acknowledges UM's statement that the complainant failed to respond to UM's request to review medical records pertaining to the subject's alleged adverse events resulting from the research.

As a result, 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,

Carol J. Weil, J.D.
Compliance Oversight Coordinator
Division of Compliance Oversight

cc: Dr. Greg Koski, OHRP
Dr. Michael A. Carome, OHRP
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Dr. Vern Sondak IRB #7 and #8 Chair, UM
Dr. Leslie Crofford, UM