DEPARTMENT OF HEALTH & HUMAN SERVICES

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October 19, 2000

Joseph J. Ferretti, Ph.D.
Senior Vice President and Provost
The University of Oklahoma Health Sciences Center
P.O. Box 26901
Oklahoma City, Oklahoma 73190

RE: Human Research Subject Protections Under Multiple Project Assurance (MPA) M-1448

Dear Dr. Ferretti:

The Office for Human Research Protections (OHRP) has reviewed your October 13, 2000 progress report on institutional protections for human subjects at the University of Oklahoma Health Sciences Center (UOHSC).

OHRP Findings

Based upon its review, OHRP finds that the UOHSC has markedly enhanced its system for protection of human subjects. Among the many enhancements noted by OHRP are the following:

(1) Officials from the UOHSC at the highest levels have demonstrated a strong commitment to the protection of human subjects and have affirmed the need for all individuals involved in the conduct of human subject research at the UOHSC to assume responsibility for ensuring that all subjects are adequately protected.

(2) The UOHSC has implemented a multifaceted education program to ensure that all Institutional Review Board (IRB) members, all IRB staff, and all research investigators and staff are educated on an ongoing basis about the ethical principles and regulatory requirements for the protection of human subjects.

(3) All human subject research previously approved by the now disbanded IRB at the UOHSC Tulsa campus is being re-reviewed by one of the newly constituted and educated IRBs at the Oklahoma City campus. OHRP acknowledges that the IRBs at the Oklahoma City campus include representation from the Tulsa campus and local Tulsa community.

(4) The UOHSC has established a full-time position of "Clinical Research Education Coordinator."

(5) The UOHSC is developing an enhanced computer database for monitoring IRB-approved research protocols.

(6) The UOHSC has revised and expanded its written IRB policies and procedures in response to OHRP's prior guidance.

(7) The minutes of recent IRB meetings clearly document substantive and meaningful initial and continuing review of human subject research.

(8) The UOHSC has established a full-time position of "Compliance Officer" within its Office of Research Administration to coordinate a quality assurance and compliance program.

Furthermore, OHRP finds that the UOHSC has adequately completed all required actions stipulated by OHRP in its June 29, 2000 letter.

As a result of the above findings, effective immediately, OHRP has removed the restriction on the UOHSC Multiple Project Assurance (MPA M-1448) and is closing its compliance oversight investigation of this matter.

Please note that the XB restriction for IRB-01 and IRB-03 has been removed by OHRP.

Additional OHRP Guidance Regarding the UOHSC IRB Policies and Procedures

At this time, OHRP would like to provide the following additional guidance regarding the UOHSC's revised IRB policies and procedures:

(1) Page 2, paragraph D.5 - Please note that when continuing review does not occur by the date specified by the IRB, IRB approval **expires** automatically. Such expiration of IRB approval does not need to be reported to OHRP as a suspension of IRB approval under HHS regulations.

(2) Page 5, paragraph 6 - This paragraph appears to reflect some confusion about the difference between the requirements for waiver of consent [see 45 CFR 46.116(d)] and the requirements for waiver of the documentation of informed consent [see 45 CFR 46.117(c)]. OHRP recommends this section of the IRB procedures be revised to more clearly distinguish these two types of waivers.

(3) Page 7, paragraph E.1 - This paragraph should be revised as follows: "A majority of the members of the IRB, including at least one member whose primary concerns are in nonscientific areas, must be present for the IRB to transact business."

OHRP appreciates the commitment of the UOHSC to the protection of human subjects. Do not hesitate to contact me should you have any questions.

Sincerely,

Michael A. Carome, M.D.
Director, Division of Compliance Oversight

cc: Senator David Boren, President, The University of Oklahoma
Mr. Joseph Harroz, Jr., General Counsel, The University of Oklahoma
Ms. Nancy Nisbett, Director, Office of Research Administration, UOHSC
Dr. Ken Lackey, President, UOHSC-Tulsa
Dr. Joan Walker, Chair, IRB-01 and -03, UOHSC
Dr. Karen Beckman, Chair, IRB-02, UOHSC
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