DEPARTMENT OF HEALTH & HUMAN SERVICES

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January 31, 2001

Walter W. Sullivan, Ph.D.
Vice President for Operations and Planning
Morehouse School of Medicine
720 Westview Drive, S.W.
Atlanta, Georgia 30310-1495

RE: Human Research Subject Protections Under Multiple Project Assurance (MPA) M-1513

Dear Dr. Sullivan:

The Office for Human Research Protections (OHRP) has reviewed your report dated September 25, 2000 regarding Morehouse School of Medicine's (MSM's) system for protection of human subjects that was submitted in response to OHRP's letter of August 7, 2000.

Based upon its review of the materials submitted with your report, OHRP finds that the MSM has developed satisfactory written IRB policies and procedures and adequately addressed the concerns set forth in OHRP's August 7, 2000 letter.

As a result of the above determination, there should be no need for further involvement of OHRP in the above referenced matters. However, MSM must notify OHRP promptly of any new information that might alter this determination.

At this time, OHRP would like to provide the following additional recommendations and guidance:

(1) Regarding item I., page 12, of the MSM policies and procedures, Reporting Proposed Changes in a Research Protocol, OHRP notes the statement that any proposed change "which affects human subjects" must be reported and reviewed by the IRB. HHS regulations at 45 CFR 46.103(b)(4)(iii) require that the IRB review and approve **all** proposed changes in a research activity, during the period for which IRB approval has already been given, prior to initiation of such changes, except when necessary to eliminate apparent immediate hazards to the subjects. Changes in research activities are not limited

to those "which affects the human subjects" and include all changes to protocols and informed consent documents. OHRP recommends that the MSM amend its written IRB policies and procedures to reflect this distinction.

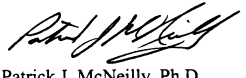
(2) Regarding item L., page 13, Reporting Non-Compliance with IRB Guidelines, OHRP notes that incidents of non-compliance which are brought to the attention of the IRB will also be brought to the attention of the department heads, the Office of Research and Development and the Office of Sponsored Program. HHS regulations at 45 CFR 46.103(a) and 46.103(b)(5) require reporting to the IRB, appropriate institutional officials, and the Federal Department or Agency head, and OHRP of any unanticipated problems involving risks to subjects or others or any serious or continuing noncompliance with 45 CFR Part 46. OHRP recommends that MSM revise its written IRB policies and procedures to reflect this requirement.

(3) OHRP notes that the discussion, on page 17 of the IRB polices and procedures, regarding the IRB waiver of informed consent stated that, among the determinations the IRB must make prior to granting the waiver, is "... d) if possible, the subject will be fully informed after the project has been completed." HHS regulations at 45 CFR 46.116(d)(4) require that the IRB must find and document that, whenever appropriate, the subjects will be provided with additional pertinent information after participation. As such, pertinent information may need to be provided to the subjects after their participation, but prior to the completion of the project.

(4) Regarding item E., page 22, IRB Authority, the IRB policies and procedures stated that, "The IRB shall immediately notify (verbally and in writing) investigators regarding decisions to suspend or terminate human subjects research activities." HHS regulations at 45 CFR 46.103(a) and 46.103(b)(5) require reporting to the IRB, appropriate institutional officials, and the Department of Agency head and OHRP of any suspension or termination if IRB approval. The MSM should revise its written IRB policies and procedures to reflect these requirements.

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
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cc: Mr.John C. Smith, IRB Administrator, MSM
Dr. Ralph W. Trottier, IRB Chair, MSM

Dr. Sandra Harris-Hooker, Director of Research Development, MSM
Commissioner, FDA
Dr. David Lepay, FDA
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