DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

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August 6, 2001

Kenneth L. Dretchen, Ph.D.
Director, Office of Regulatory Affairs
Georgetown University
3900 Reservoir Road, N.W.
NW103 Medical-Dental Building
Washington, D.C. 20007

RE: Human Research Subject Protections Under Multiple Project Assurance (MPA) M-1255

Research Project: Race and Gender Differences in Clinical Decision Making
IRB Project Number: 113-94
HHS Project Number: R01 HS07135
Principal Investigator: Kevin Schulman, M.D.

Dear Dr. Dretchen:

The Office for Human Research Protections (OHRP) has reviewed your report of July 31, 2001, regarding the above referenced research project conducted by Georgetown University (GU).

Based upon its review of the documents provided with your report, OHRP finds that the corrective actions taken by GU adequately address OHRP's findings and concerns regarding the above referenced research project and are appropriate under the GU Multiple Project Assurance. As a result, OHRP is closing this case and 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.

At this time, OHRP provides the following additional guidance:

> Continuing IRB review of research should be substantive and meaningful. In conducting continuing review of research not eligible for expedited review, all IRB members should at least receive and review a protocol summary and a status report on the progress of the research, including (a) the number of subjects accrued; (b) a description of any unanticipated problems involving risks to subjects or others and of any withdrawal of

subjects from the research or complaints about the research; (c) a summary of any recent literature, findings obtained thus far, amendments or modifications to the research since the last review, reports on multi-center trials and any other relevant information, especially information about risks associated with the research; and (d) a copy of the current informed consent document. Primary reviewer systems may be employed, so long as the full IRB receives the above information. Primary reviewers should also receive a copy of the complete protocol including any modifications previously approved by the IRB (see OPRR Reports 95-01). Furthermore, the minutes of IRB meetings should document separate deliberations, actions, and votes for each protocol undergoing continuing review by the convened IRB.

OHRP appreciates your institution's continued commitment to the protection of human research subjects. Do not hesitate to contact me if you have any questions regarding this matter.

Sincerely,

Kristina C. Borror, Ph.D.
Compliance Oversight Coordinator
Division of Compliance Oversight

cc: Mrs. Elizabeth Crigler, Executive Officer, IRB, GU
Dr. Willard A. Barnes, Chair, IRB, GU
Commissioner, FDA
Dr. David Lepay, FDA
Dr. James F. McCormack, FDA
Dr. Greg Koski, OHRP
Dr. Melody H. Lin, OHRP
Mr. George Gasparis, OHRP
Dr. Jeffrey M. Cohen, OHRP
Mr. Barry Bowman, OHRP