DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

FOR US POSTAL SERVICE DELIVERY:
Office for Human Research Protections
6100 Executive Boulevard, Suite 3B01
National Institutes of Health (MSC 7507)
Rockville, Maryland 20892-7507

FOR HAND DELIVERY OR EXPRESS MAIL:
Office for Human Research Protections
6100 Executive Boulevard, Suite 3B01
Rockville, Maryland 20852

Telephone: 301-402-5567
FAX: 301-402-2071
E-mail: mc2a@nih.gov

October 3, 2000

Lois B. DeFleur
President
State University of New York at Binghamton
P.O. Box 6000
Binghamton, New York 13902-6000

Frances Carr
Vice Provost for Research and Graduate Studies
State University of New York at Binghamton
P.O. Box 6000
Binghamton, New York 13902-6000

RE: Human Research Subject Protections Under Multiple Project Assurance (MPA) M-1209

Research Projects: Exploring Racism in Broome County; Job Seeking, Discouragement and Race; Messages About Job Possibilities in the Southern Tier
Principal Investigator: Dr. Jane Connor

Dear Dr. DeFleur and Dr. Carr:

The Office for Human Research Protections (OHRP), formerly the Office for Protection from Research Risks (OPRR), has reviewed your March 29, 1999 report regarding the above referenced research activities. OHRP apologizes for the delay in its response.

In its February 16, 1999 letter, OHRP requested that the State University of New York at Binghamton (SUNY-Binghamton) investigate and respond to the allegation that the SUNY-Binghamton Institutional Review Board (IRB) was not sufficiently qualified through the experience and expertise of its members, and the diversity of the members including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects, as required by HHS regulations at 45 CFR 46.107(a).

Based upon its review of your report, OHRP finds that the SUNY-Binghamton IRB satisfies the membership requirements stipulated by HHS regulations at 45 CFR 46.107. In particular, while OHRP acknowledges that the assessment of the adequacy of the diversity of IRB membership is a very subjective process, it appears that since at least September 1998, the SUNY-Binghamton IRB has had adequate diversity with respect to race, gender, and cultural backgrounds. Furthermore, OHRP notes that

Dr. Connor's protocols entitled *Job Seeking, Discouragement and Race* and *Messages About Job Possibilities in the Southern Tier* were reviewed and approved by the IRB in October 1998 and February 1999, respectively.

As a result of the above determination, 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.

Additional OHRP Guidance

At this time, OHRP would like to provide the following additional guidance regarding SUNY-Binghamton's system for protecting human subjects:

(1) HHS regulations at 45 CFR 46.107(e) stipulate that no IRB member may participate in the initial or continuing review of any project in which the member has a conflicting interest.

In reviewing the curriculum vitae of IRB members that were submitted with your report, OHRP notes that Mr. Stephen Gilje, the Chair of the IRB, and Ms. Deanna Fix France, the Associate Chair of the IRB, are senior staff within the Office of Research and Sponsored Programs. OHRP is concerned that having such staff from the Office of Research and Sponsored Programs serve as IRB members may create significant real or apparent conflicts of interests. OHRP strongly recommends that SUNY-Binghamton submit to OHRP a revised IRB membership roster that does not include Mr. Gilje and Ms. France. Alternatively, if SUNY-Binghamton chooses not to revise its IRB membership roster, please submit a written explanation of why having these individuals serve as IRB members does not create real or apparent conflicts of interest. This explanation should be submitted to Dr. J. Thomas Puglisi, Director, Division of Policy and Assurance, OHRP, no later than October 31, 2000.

(2) Continuing IRB review of research must 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 adverse events or 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.

When conducting research under an expedited review procedure, the IRB Chair (or designated IRB member(s)) should receive and review all of the above referenced documentation.

OHRP strongly recommends that SUNY-Binghamton evaluate the continuing review procedures of its IRB to ensure conformance with the above guidelines.

(3) HHS regulations at 45 CFR 46.115(a)(2) require that the minutes of IRB meetings document the vote on all IRB actions including the number of members voting for, against, and abstaining. In order to document the continued existence of a quorum, OHRP strongly recommends that votes be recorded in the minutes using the following format: Total = 15; Vote: For-14, Opposed-0, Abstained-1 (NAME). OHRP notes that simply recording votes as "unanimous" is not sufficient.

(4) Where HHS regulations require specific findings on the part of the IRB, such as (a) approving a procedure which alters or waives the requirements for informed consent [see 45 CFR 46.116(d)]; (b) approving a procedure which waives the requirement for obtaining a signed consent form [see 45 CFR 46.117(c)]; (c) approving research involving prisoners (see 45 CFR 46.305-306); or (d) approving research involving children (see 45 CFR 46.404-407), the IRB should document such findings. OHRP strongly recommends that all required findings be fully documented in the IRB minutes, including protocol-specific information justifying each IRB finding.

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,

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

Enclosure: OPRR Reports 95-01

cc: Mr. Stephen A. Gilje, SUNY-Binghamton
Dr. Jane Connor, Department of Psychology, SUNY-Binghamton
Commissioner, FDA
Dr. David Lepay, FDA
Dr. James F. McCormack, FDA
Dr. Greg Koski, OHRP
Dr. Melody H. Lin, OHRP
Dr. J. Thomas Puglisi, OHRP
Dr. Katherine Duncan, OPRR
Ms. Freda Yoder, OPRR
Dr. Jeffrey M. Cohen, OHRP
Dr. Clifford C. Scharke, OHRP
Mr. Barry Bowman, OHRP