



Office for Human Research Protections  
The Tower Building  
1101 Wootton Parkway, Suite 200  
Rockville, Maryland 20852

Telephone: 301-402-5567  
FAX: 301-402-2071

E-mail: mcarome@osophs.dhhs.gov

May 31, 2002

John M. Allen  
Assistant Vice President for Scientific Affairs  
State University of New York Downstate Medical Center  
450 Clarkson Avenue, Box 129  
Brooklyn, New York 11203-2098

**RE: Human Research Subject Protections Under Multiple Project Assurance (MPA) M-1073**

Dear Mr. Allen:

The Office for Human Research Protections (OHRP) has reviewed your May 16, 2002 letter responding to the findings made by OHRP during its April 15-16, 2002 not-for-cause compliance oversight site visit to the State University of New York Downstate Medical Center (SUNY Downstate).

OHRP has determined that the corrective actions taken by SUNY Downstate adequately address OHRP's findings and concerns.

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.

At this time, OHRP provides the following additional guidance:

Regarding SUNY Downstate's policy entitled "Enrolling Participants Who are Illiterate or do Not Speak English," OHRP notes the following statement:

"Studies targeting or otherwise expecting to enroll large numbers of participants who do not speak English should make plans to address consent. Specifically, the consent form should be translated and the translation IRB approved."

Please note that translation of informed consent documents should not be limited to studies where only “large number” of participants who do not speak English is expected.

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

cc: Mr. John O’Hara, Research Foundation of SUNY Downstate  
Dr. Eli Friedman, Chair, IRBs, SUNY Downstate  
Dr. Enzo Bard, IRB Administrator, SUNY Downstate  
Ms. Ruth Brown, Executive Director, Arthur Ashe Institute  
Dr. Charles Hyman, Associate Medical Director, Kings County Hospital Center  
Commissioner, FDA  
Dr. David Lepay, FDA  
Dr. Greg Koski, OHRP  
Dr. Melody H. Lin, OHRP  
Dr. Jeffrey Cohen, OHRP  
Mr. George Gasparis, OHRP  
Ms. Yvonne Higgins, OHRP  
Mr. Barry Bowman, OHRP