

NEW YORK MEDICAL COLLEGE

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March 27, 2007

Michelle Johnson-Lancaster
IBC Coordinator
U.S. Department of Health and Human Services
Public Health Service
Office of Biotechnology Activities
National Institute of Health
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Dear Ms. Johnson-Lancaster:

This is in response to the letter of February 20, 2007, which was received on February 27, 2007, from Dr. Amy P. Paterson, Director, regarding, in substance, a complaint filed with your office by the Sunshine Project relative to an alleged request by such group for the minutes of the College's Institutional Biosafety Committee ("IBC").

I have reviewed the matter and have concluded that the minutes of the IBC were not provided as requested because most of the recombinant DNA molecules involved at New York Medical College is exempt under the NIH Guidelines for Research Involving Recombinant DNA Molecules and thereby is not subject to registration with nor review by the College's IBC. In addition, I understand that nonexempt retro and adenoviruses recombinant DNA molecules have been individually reviewed and examined by Dr. Felipe Cabello, Professor of the Department of Microbiology and Immunology and Chairman of the College's IBC, pursuant to delegation by the IBC in 2001. Dr. Cabello has continued to perform such responsibility inasmuch as the IBC determined that such DNA molecules are not high risk, the cloning vectors are very well characterized and most are commercially available, the manipulations carried out were minimal and did not alter the cloning vector, the experiments use very small volumes-less than the 10 liters stipulated in the NIH Guidelines for Research Involving Recombinant DNA Molecules and the viruses are replication incompetent and thereby cannot infect humans or animals. Since the delegation, there has been no major change to the characteristics in the reviewed research using such nonexempt recombinant DNA molecules. Consequently, since the research was evaluated by Dr. Cabello consistent with the delegation and there was no significant deviation from the characteristics of the experimental viruses, the IBC did not review such research and thus there are no minutes.

I trust that the above is satisfactory. Please contact me if you have any questions on the above.

Angela C. Birnbaum

ery truly yours,

Biological Safety Officer

Department of Environmental Health and Safety

cc: Felipe Cabello, M.D. Edward Hammond