



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare
6700B Rockledge Drive, Suite 2500, MSC 6910
Bethesda, Maryland 20892-6910
Home Page: <http://grants.nih.gov/grants/olaw/olaw.htm>

FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare
6700B Rockledge Drive, Suite 2500
Bethesda, Maryland 20817
Telephone: (301) 496-7163
Facsimile: (301) 480-3387

October 19, 2021

Re: Animal Welfare Assurance
#A3354-01 (OLAW Case 1X)

[REDACTED]
Executive Director of Regulatory Support
Institutional Official
State University of New York - University of Buffalo
[REDACTED]
Buffalo, NY 14260

Dear [REDACTED],

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your October 12, 2021 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the State University of New York - University of Buffalo following up on an initial September 1, 2021 notification by email.

According to the information provided, this Office understands that the University of Buffalo Animal Care and Use Committee (ACUC) determined that instances of noncompliance occurred with respect to: protocol suspension due to animal welfare concerns. It is understood that on August 13, 2021, 10 out of 19 mice were placed on veterinary report for large, ulcerative skin lesions. The Laboratory Animal Facilities Veterinary staff reported this as a serious ongoing issue with the application of the chemotherapy drug, cabazitaxel, plus DMSO that is potentially causing chemical burns to the mice. On August 16, 2021, the committee reviewed animal welfare concerns associated with the application of cabazitaxel including the vehicle DMSO. The committee unanimously voted to suspend the protocol.

The final report states on September 20, 2021, the protocol suspension was lifted when the Principal Investigator (PI) submitted an amendment to remove the experiment which includes the application of cabazitaxel, along with DMSO. The PI decided to cease all topical studies, as at this time no further studies are needed. It is understood the IACUC will work with the PI to proactively address these animal welfare concerns if future topical studies with cabazitaxel ointment are proposed.

It is noted that this research is supported by PHS funding. Based on its assessment of this explanation, OLAW understands that the State University of New York - University of Buffalo has implemented appropriate measures to correct and prevent recurrences of these problems and is now compliant with provisions of the PHS Policy. We appreciate being informed of these matters and find no cause for further action by this Office.

Sincerely,
Jacquelyn T.
Tubbs -S

Jacquelyn Tubbs, DVM, DACLAM
Animal Welfare Program Specialist
Division of Compliance Oversight
Office of Laboratory Animal Welfare

Digitally signed by Jacquelyn
T. Tubbs -S
Date: 2021.10.19 14:31:37
-04'00'

cc: IACUC Contact