



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive – MSC 7982
Bethesda, Maryland 20892-7982
Home Page: <http://grants.nih.gov/grants/olaw/olaw.htm>

FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive
Bethesda, Maryland 20817
Telephone: (301) 496-7163
Facsimile: (301) 402-7065

April 5, 2017

Re: Animal Welfare Assurance
#A3100-01 [OLAW Case 1G]

Ms. Nancy Lewis
Assistant Vice President for Research
SUNY-Binghamton
P.O. Box 6000
Binghamton, NY 13902-6000

Dear Ms. Lewis

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your March 28, 2017 letter regarding noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Binghamton University – State University of New York. It was reported that the associated animal activities were not NIH funded. According to the information supplied, OLAW understands that two independent instances of noncompliance for failure to adhere to the approved protocol were noted following a blizzard that led to University and road closures during an issued State of Emergency on March 14 -15, 2017.

The first instance of noncompliance was discovered on March 15, 2017 when one animal was found dead and three required post-operative records for rats post-intravenous catheterization surgery were missing assessment data for March 14, 2017. On these days, the rats did not receive their analgesics, antibiotics or catheter flushes as scheduled. Following an April 4, 2017 phone call with attending veterinarian, Dr. Kal-Downs, OLAW also understands that the lack of post-operative monitoring was regarded as a contributing factor to the animal death.

The second instance of noncompliance was discovered on March 16, 2017 when the three preceding days of required mouse tumor assessment records were incomplete.

Corrective actions included notification of both investigators and a reminder was sent to all Investigators that post-procedural assessments and care, as described in the protocol, must be performed regardless of University closure or weather. It was emphasized that personnel responsible for assessments and care must ensure that these actions are completed and if personnel are unable to complete these assessments, the PI and if necessary, the Laboratory Animal Resources department should be contacted for assistance. The IACUC discourages performing surgery prior to a hazardous weather warning and recommends that each lab have an emergency plan. It was indicated that this information will be reiterated to researchers.

Based on the information provided, OLAW accepts the corrective actions and agrees that it is important for the Binghamton University research community to understand their responsibilities to ensure appropriate care is provided for the laboratory animals at all times. Although these activities were not NIH funded, the application of the standards of the PHS Policy across the animal care and use program reduces any potential appearance of a double standard. We appreciate being informed of these matters and find no cause for further action by this Office.

Page 2 – Ms. Lewis
April 5, 2017
OLAW Case A3100-1G

Sincerely,

A handwritten signature in black ink, appearing to read 'Jane Na', with a stylized flourish at the end.

Jane Na, DVM
Veterinary Medical Officer, OLAW
Office of Laboratory Animal Welfare
Division of Compliance Oversight

cc: IACUC Chair

March 28, 2017

Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
Rockledge 1, Suite 360, MSC 7982
6705 Rockledge Drive
Bethesda, MD 20892-7982

Dear Director,

Binghamton University, in accordance with PHS Assurance #D16-00063, is reporting two independent instances of noncompliance for failure to adhere to the approved protocol on non-NIH funded projects. Both incidents were attributed to a recent blizzard in which over 30 inches of snow fell, prompting the University and all local roads closed during an issued State of Emergency on March 14 -15, 2017.

On March 15, 2017, three post-operative records were missing assessment data for March 14, 2017, on rats that had intravenous catheterization surgery on March 13, 2017. Post-operative assessments are required daily for a minimum of three days beginning after recovery from anesthesia. On these days, the rats did not receive their analgesics, antibiotics or catheter flushes as scheduled, and one animal was found dead.

On March 16, 2017, review of an assessment record for mice with developing tumors found the record incomplete for the three preceding days. This daily record is required to demonstrate that humane endpoints are followed when animals have a tumor burden.

Both Investigators were notified. As a result, the IACUC reminded all Investigators that post-procedural assessments and care as described in the protocol must be performed regardless of University closure or weather. Personnel responsible for assessments and care must ensure this is completed, especially if they are personally unable to fulfill their responsibilities. This includes contacting their Principal Investigator, and if necessary, the Laboratory Animal Resources department for assistance.

An emergency plan for each lab is highly recommended. The IACUC also discourages performing surgery in advance of a hazardous weather warning. The IACUC will reiterate these recommendations to all Investigators to ensure compliance and that proactive measures are instituted.

Please feel free to contact us for more information and we appreciate your guidance to prevent any future instances of noncompliance.

Sincerely,

A handwritten signature in cursive script, reading "Nancy L. Lewis".

Nancy L. Lewis
Assistant Vice President for Research Compliance
Institutional Official

cc: Dr. C. Bishop, IACUC Chair
Dr. K. Kal-Downs, Attending Veterinarian

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, March 31, 2017 7:27 AM
To: 'Nancy L Lewis'
Subject: RE: Binghamton University-noncompliance report

Thank you for this report, Ms. Lewis. We will respond soon.

Axel Wolff, M.S., D.V.M.
Director, Division of Compliance Oversight
OLAW

From: Nancy L Lewis [mailto:nlewis@binghamton.edu]
Sent: Thursday, March 30, 2017 5:07 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: Binghamton University-noncompliance report

Director,

Binghamton University, in accordance with PHS Assurance #D16-00063, respectfully reports two independent instances of noncompliance for failure to adhere to an approved protocol on non-NIH funded projects.

Please do not hesitate to contact me should you have any questions.

Thank you,

Nancy Lewis
Assistant Vice President for Research Compliance
Institutional Official
Binghamton University
Ph. [Redacted]
Fax. [Redacted]
nlewis@binghamton.edu



Division of Compliance Oversight

Record of Call for Case # A3100-16 (D16-00063)

Date & Time	Message	Initials
4/4/17 2:45 PM	Dr. Kal-Downs, attending veterinarian, indicates the rat found dead was associated with lab staff not performing post-op checks due to the blizzard. She felt that appropriate intervention would have been able to be provided if the post-op checks were performed per IACUC protocol.	T JN I