



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) 402-7065

May 19, 2022

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

Ms. Nancy L. Lewis
Assistant Vice President for Research Compliance
State University of New York - Binghamton
P.O. Box 6000
Binghamton, NY 13902-6000

Dear Ms. Lewis,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your April 27, 2022 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals within the animal care and use program at Binghamton University. According to the information provided, OLAW understands that 16 rats were placed in ethanol vapor chambers overnight per an approved protocol. The next morning most of the animals were recumbent and hyperpnic. Fourteen animals recovered when the chambers were opened, but 2 rats remained unresponsive and were pronounced dead. Necropsy findings from the deceased animals were consistent with suffocation from inadequate oxygen and elevated carbon dioxide. The principal investigator (PI) concluded that the chamber timers were mistakenly set for an incorrect day, resulting in no air flow to the chambers for 12 hours. The rats involved in this incident were supported by PHS funds.

Corrective and preventive measures included several changes implemented by the PI. A checklist was created for the process of setting up the chambers, which will be filled out and initialed by the attending laboratory member each time the chambers are used. A second laboratory member will confirm that the checklist is accurate and ensure setup is correct. A third laboratory member will ensure that the chambers are running properly after the experiment is underway. In addition, documentation confirming correct timer scheduling will be signed by the attending laboratory member. This document will be reviewed and initialed by a second laboratory member confirming correct timer configuration. The PI submitted a protocol amendment outlining these precautions which has been approved by the Institutional Animal Care and Use Committee (IACUC).

OLAW appreciates the consideration of this matter by Binghamton University, which was consistent with the philosophy of institutional self-regulation. Based on the information provided, OLAW is satisfied that appropriate actions have been taken to investigate this incident and prevent recurrence. We appreciate being informed of this matter and find no cause for further action by this office.

Sincerely,

Robyn M. Engel -S

Digitally signed by Robyn M. Engel -S
Date: 2022.05.19 11:32:26 -0400

Robyn M. Engel, DVM
Animal Welfare Program Specialist
Office of Laboratory Animal Welfare

cc: IACUC contact

A3100-1P



THE OFFICE OF RESEARCH COMPLIANCE
ASSISTANT VICE PRESIDENT FOR RESEARCH COMPLIANCE
PO Box 6000
BINGHAMTON, NEW YORK 13902-6000
NLEWIS@BINGHAMTON.EDU
TELE: (607) 777-3532

April 27, 2022

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** and PHS Policy IV.F3, is reporting incidents of noncompliance associated with NIH funding award numbers AA017823, AA028228 and AA023874. This incident occurred on March 2, 2022 and involved rats undergoing air or ethanol exposure in vapor inhalation chambers. The aim protocol is to investigate changes in chemicals in the brain (dopamine, norepinephrine, and serotonin) in animal models of anxiety and pain, and to investigate brain correlates of drug and anxiety interactions, as well as alcohol and pain interactions via ethanol vapor inhalation.

During an experiment, a cohort of 16 animals was placed in the ethanol vapor chambers overnight per an approved protocol. At 7:30 a.m., an Animal Caretaker found the "air only" and ethanol vapor chambers filled with moist air. The Principal Animal Caretaker and Associate Director of Laboratory Animal Resources were notified and responded finding most of the animals in recumbent positions and hyperpnic. The Veterinary Technician was consulted and concurred the animals were in distress. The doors to the chambers were immediately opened and no alcohol odor emitted from the chambers. Fourteen of the animals responded by lifting their noses and bodies toward the cage lid and began normal respirations. This response indicated lack of airflow through the apparatus. Two animals did not respond and pronounced dead by the Veterinary Technician. The remaining animals stabilized. Gross necropsy of the two deceased animals identified diffuse pulmonary emboli, consistent with findings of suffocation from inadequate oxygen and elevated carbon dioxide.

The PI was notified and was very responsive in addressing this incident. Upon investigation, she concluded that the chamber timers, which are usually set to run each evening from 8 p.m. to 8 a.m., were mistakenly set for an incorrect day, resulting in air flow in the chambers not engaged for a 12 hour period. This assessment was confirmed by the level of ethanol in the flask not having changed volume from the previous afternoon. In response to the incident, the PI implemented several changes. A checklist was created for the process of setting up the chambers to be filled out and initialed each time the chambers are set by the attending lab member. A second lab member will confirm the checklist for accuracy and ensure the setup is correct. A third member of the lab will ensure that the chambers are running correctly soon after 8 p.m. In addition, documentation confirming correct timer scheduling will be signed by the attending lab member. This document will be reviewed and initialed by a second lab member confirming correct timer configuration. The PI submitted a protocol amendment delineating these presentative measures. This amendment was approved by the IACUC on 4/22/2022.

Please contact me if you have any questions or would like additional information. We appreciate your guidance in preventing future similar instances.

Respectfully

Digitally signed by Nancy Lewis
Date: 2022.04.27 10:27:28 -04'00'
Adobe Acrobat DC version: 2015.006.30527

Nancy Lewis, M.A., CRA, CIP
Assistant Vice President for Research Compliance/IO

cc: Dr. C. Bishop, IACUC Chair
Dr. M. Martin, Attending Veterinarian (interim)

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, April 29, 2022 7:24 AM
To: Nancy L Lewis
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: [EXTERNAL] Binghamton University-Report of Noncompliance

Thank you for this report, Dr. Lewis. We will send a response soon.

Axel Wolff, M.S., D.V.M.
Deputy Director, OLAW

From: Nancy L Lewis <nlewis@binghamton.edu>
Sent: Wednesday, April 27, 2022 10:35 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Christopher R Bishop <cbishop@binghamton.edu>; Mary Martin <mmartin@binghamton.edu>
Subject: [EXTERNAL] Binghamton University-Report of Noncompliance

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Director,

Binghamton University, in accordance with PHS Assurance #D16-00063 and PHS Policy IV.F3, is reporting one incident of noncompliance associated with NIH Awards AA017823, AA028228 and AA023874. Included in this report are the mitigations that were implemented addressing the disclosed incident.

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

Respectfully,

Nancy Lewis, M.A., CRA, CIP
Assistant Vice President for Research Compliance/IO
Binghamton University
BI2203
Ph. (b) (6)
nlewis@binghamton.edu
<https://www.binghamton.edu/research/compliance/>
pronouns: she, her, hers