



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
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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) 480-3387

January 13, 2022

Re: Animal Welfare Assurance
#A3100-01 [OLAW Case 10]

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 December 6, 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 - Binghamton. This letter had not been preceded by a preliminary report to OLAW.

According to the information provided, this Office understands that the Binghamton University Animal Care and Use Committee (ACUC) determined that instances of noncompliance occurred with respect to: the conduct of an unapproved procedure, the death and required euthanasia of rats. The final report states two incidents of noncompliance occurred within the same lab. The first incident involved 8 rats that were exposed to ethanol vapor in two inhalation chambers overnight as per the protocol. After the session, one animal was found dead and supportive care was provided to the surviving animals that were comatose with labored breathing. Ultimately, the remaining rats were euthanized because they did not regain consciousness. It was determined the animals were inadvertently overdosed due to a setup problem with the chambers. The second incident involved the same cohort of animals, which underwent blood collection via tail snip technique. This procedure was not an approved protocol procedure. It is understood a tail nick procedure was approved on an associated protocol.

In response to these incidents, the Principal Investigator (PI) agreed to retraining of all lab members. The PI retrained lab members on October 1, 2021 in ethanol vapor chamber procedures and documented the procedures for lab reference. Also, the veterinary technicians provided refresher retraining on identifying signs of distress in animals and proper reporting procedures once signs are discovered. It is understood that all personnel listed on the protocol attended both sessions. The renewal of the protocol included additional detail for setting up the ethanol vapor chambers and tail snip blood collection method. The renewal was approved on October 21, 2021, and the PI ensured all lab personnel performing protocol procedures reviewed the renewed protocol.

It is noted that this research is supported by funding from NIH. Based on its assessment of this explanation, OLAW understands that the State University of New York - Binghamton has implemented appropriate measures to correct and prevent recurrences of these problems and is now compliant with provisions of the PHS Policy.

Page 2 – Ms. Lewis
November 19, 2020
OLAW Case A3100-10

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
Senior Animal Welfare Program Specialist
Division of Compliance Oversight
Office of Laboratory Animal Welfare

Digitally signed by
Jacquelyn T. Tubbs -S
Date: 2022.01.13
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cc: IACUC Contact



A3100-10

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

December 6, 2021

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 two incidents of noncompliance associated with NIH funding award number AA017823. These incidents involved rats that were administered ethanol vapor treatments during experimental testing on August 26, 2021. A full investigation was conducted by the IACUC Chair and brought to the IACUC resulting in this reporting of noncompliance.

The goal of the protocol related to this reporting is to investigate changes in neurochemicals (dopamine, norepinephrine, and serotonin) in animal models of anxiety and pain, and to investigate brain correlates of drug and anxiety interaction, as well as alcohol and pain interactions. To understand and achieve these goals, rats are exposed to ethanol in vapor inhalation chambers.

The first reported instance of noncompliance occurred during an experiment whereby a cohort of eight animals at one time were exposed to ethanol vapor in 2 inhalation chambers overnight per an approved protocol. Following the session, one animal was found dead and seven were comatose with labored breathing. One of the seven died prior to receiving supportive care. The six surviving animals were immediately given supportive care and were carefully monitored. They were stabilized with normal temperature, heart, and respiratory rates, but were euthanized several hours later when they did not regain consciousness.

The PI was very responsive to addressing this incident. Upon investigation, it was concluded that the animals were inadvertently overdosed due to a setup problem with the chambers. The two flasks containing the ethanol were not set at the proper angle causing excessive ethanol ventilated into the chambers.

The second reported instance involved protocol procedure deviation. The previously mentioned eight animals had blood withdrawn to measure their blood ethanol levels by a research assistant. Although there were no observable adverse effects from the collection, it was noticed that a tail snip technique was used. This procedure was not an approved protocol procedure. A tail nick procedure was the approved procedure within the associated protocol.

While the PI had written documented training records on tail blood collections and vapor chamber procedures, she agreed to have all lab members re-trained. The PI re-trained lab members on October 1, 2021 in ethanol vapor chambers procedures and carefully documented the procedures for lab reference. The Veterinary Technicians from Laboratory Animal Resources provided refresher training on recognizing signs of distress in animals and proper reporting procedures once signs are discovered. This training session was held on October 1, 2021, as well. All personnel listed on the protocol attended both sessions.

The renewal of this protocol was reviewed with final approval issued on October 21, 2021. Additional detail for setting up the ethanol vapor chambers and the tail snip blood collection procedure were included in this protocol renewal. To ensure only one mm is transected during the tail snip, a small ruler must be used. Subsequent collections are taken using a sterile scalpel or sharp scissor to nick the scab. In addition, the Institutional Official has been informed that the PI went over the renewed protocol ensuring that all lab personnel performing protocol procedures have thoroughly read and hold a full understanding of approved protocols, and are not to engage in any procedures that have not been approved.

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

Sincerely,

Digitally signed by Nancy Lewis
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Adobe Acrobat DC version: 2015.006.30527

Nancy L. Lewis

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

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, December 10, 2021 7:34 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, Ms. 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: Monday, December 6, 2021 4:26 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Kimberly A Kal-Downs <kkal@binghamton.edu>; Christopher R Bishop <cbishop@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 two incidents of noncompliance associated with NIH Award AA017823.

Included in this report are the mitigations that were implemented addressing the disclosed incidents.

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

Respectfully,

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