



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

June 27, 2022

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

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 May 24, 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 3 one-day old rat pups were unintentionally left in a cage without their dam overnight. During regular colony maintenance, newly born pups were being culled to control litter size per the approved protocol. The 3 pups were separated for euthanasia, but the laboratory technician forgot about the cage after the light timer turned off. The pups were euthanized the next day after the animal caretaker notified the laboratory. The rats involved in this incident were supported by PHS funds.

Corrective and preventive measures included changes implemented by the Principal Investigator (PI). Colony maintenance and culling will be done fully in the light cycle and prior to running behavioral testing. This modification in scheduling will increase the number of laboratory personnel monitoring procedures. The PI discussed the incident and remediation with the study team to ensure full compliance.

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: 2022.06.27 11:12:10 -04'00'

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

cc: IACUC contact



A3100-1R

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

May 24, 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 an incident of noncompliance associated with NIH funding award number AA019972-11. This incident involved three (3) one-day old rat pups that were to be culled. The three pups were unintentionally left in a cage without their dam from the evening of Saturday, April 2, 2022 until the morning of Sunday, April 3, 2022.

The goal of this particular IACUC protocol is to provide animals of a certain age with similar early experience and social history for the ontogenetic studies outlined in other IACUC-approved protocols. After the IACUC investigation it was determined that during regular colony maintenance, newly born pups were being culled to control for litter size per the approved protocol. On the evening of Saturday, April 2, 2022, three pups were selected and separated into another cage to be euthanized. On the morning of Sunday, April 3, 2022, an animal caretaker found the three pups alive. Upon inspection, the pups did still have milk in their stomachs but body temperature status was not noted. The animal care taker notified the lab and the pups were euthanized immediately.

The PI was very responsive to this incident. Upon investigation, it was concluded that the lab technician performing the colony maintenance forgot about the cage after the light timer turned off. It was decided that given the limited number of individuals that may be in the animal area on the weekends, colony maintenance and culling will be done fully in the light cycle and prior to running behavioral testing. This modification in scheduling will increase lab personnel coinciding and monitoring. The PI discussed the incident and remediation the with the study team to ensure full compliance.

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

Sincerely,

(b) (6)

Nancy L. Lewis

cc: Dr. C. Bishop, IACUC Chair
Dr. M. Martin, AV

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, May 25, 2022 7:04 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. We will send a response soon.

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

From: Nancy L Lewis <nlewis@binghamton.edu>
Sent: Tuesday, May 24, 2022 10:40 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Mary Martin <mmartin@binghamton.edu>; Christopher R Bishop <cbishop@binghamton.edu>; (b) (6)
(b) (6)
Subject: [EXTERNAL] Binghamton University-Report of Noncompliance

Director,

Binghamton University, in accordance with PHS Assurance #D16-00063 and PHS Policy IV.F3, is reporting one incident of noncompliance associated with NIH Award AA019972-11. 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

(b) (4)

(b) (6)

nlewis@binghamton.edu

<https://www.binghamton.edu/research/compliance/>

pronouns: she, her, hers

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