



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

February 8, 2018

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

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 February 7, 2018 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Binghamton University. According to the information provided, OLAW understands that several rat pups had not been euthanized on the day specified in the protocol and some were underweight, cage cards were incomplete, and isoflurane was used prior to decapitation although use of the gas was not described in the protocol.

The corrective actions consisted of euthanizing the excess rats. The laboratory staff was retrained on the responsibility of the Institutional Animal Care and Use Committee (IACUC), relevant standard operating procedures, the protocol content, record keeping, decapitation procedures, and colony management. The Principal Investigator was required to periodically update the IACUC on the status of the breeding protocols.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to correct and prevent recurrence of this problem. OLAW concurs with the actions taken by the IACUC to comply with the PHS Policy.

Sincerely,

Signature

Axel Wolff, M.S., D.V.M.
Deputy Director
Office of Laboratory Animal Welfare

cc: IACUC Chair

A3100 - 1J

Division of Research

PO Box 6000
Binghamton, New York 13902-6000
607-777-6137, Fax: 607-777-4354

February 7, 2018

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 NIAAA funding award number R01AA025784-01. This incident involved rats and the failure to adhere to an IACUC-approved protocol.

A PI maintains a breeding colony of rats (Protocol 756-15 approved on 02/05/2016). The approved protocol delineates that litters will be culled to ten pups on postnatal day one (1) via rapid decapitation using sharp surgical scissors. On 12/28/2017, animal caretakers (staff) from Laboratory Animal Resources (LAR) discovered two cages of animals with 15 and 17 pups that were estimated at 5-7 days old, some appearing to be underweight. It was also noted that the cage cards were incomplete (i.e. animals not properly identified, protocol number missing, date of birth not noted). The PI was contacted immediately by the LAR staff regarding the animal status. The lab members came immediately to the facility and euthanized the underweight pups and culled the litters soon thereafter.

The IACUC Chair met with the PI to discuss the non-compliance with the approved protocol. During this discussion, the PI informed the Chair that the lab members used isoflurane before decapitation which is a procedure not included in the approved protocol. The Veterinarian met with the lab members and explained that the time it takes to anesthetize neonates can cause stress and were reminded that the goal is to euthanize the animals quickly. The Veterinarian followed up with a decapitation training session with the responsible lab members.

The IACUC Chair asked the PI to schedule a laboratory meeting to review the approved animal protocols with the lab members. The IACUC Chair offered to attend the meeting and/or answer any questions the lab members may have regarding IACUC oversight and protocol adherence. This meeting was held by the PI on 01/29/2018.

Based on issues exhibited, the PI has agreed to complete supplemental trainings on the responsibility of the IACUC (conducted by the IO on 02/07/2018), LAR SOPs applicable to the current approved breeding protocols (to be conducted by LAR staff), and proper record keeping and colony management (to be conducted by active researcher and IACUC Board member). These trainings are to be completed by 04/01/2018 and the information disseminated to her lab members and the assurance that each has full comprehension and can effectively apply the information. A synopsis and assessment of the trainings will be presented to the IACUC by each trainer to ensure the IACUC is satisfied that the PI has received the necessary information to ensure proper animal care and treatment. Additionally, the PI will be

required to report to the IACUC on a semi-annual basis on the progress of the two active breeding protocols until the IACUC is satisfied. Please do not hesitate to contact me should you have any questions or require additional information.

Sincerely,

Signature

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

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

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Thursday, February 08, 2018 8:04 AM
To: 'Nancy L Lewis'
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Binghamton University-noncompliance report

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

From: Nancy L Lewis [mailto:nlewis@binghamton.edu]
Sent: Wednesday, February 07, 2018 2:40 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: Binghamton University-noncompliance report

Director Wolff,

Binghamton University, in accordance with **PHS Assurance #D16-00063** and PHS Policy IV.F3, is reporting an incident of noncompliance associated with NIAAA funding award number R01AA025784-01 and mitigations to address the disclosed issues.

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

Respectfully,

Nancy Lewis, CRA
Assistant Vice President for Research Compliance
Binghamton University

Ph. [Phone Number]

Fax. [Phone Number]

nlewis@binghamton.edu

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