## 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

September 18, 2017

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

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 September 15, 2017 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 mice were given intragastric ethanol or water although this procedure was only approved for rats on the protocol.

The corrective action consisted of stopping the unapproved procedure and amending the protocol. The Principal Investigator was counseled and will review the content of the protocols with the laboratory staff before conducting procedures.

Based on the information provided, OLAW is satisfied that appropriate actions have been taken to investigate, correct, and prevent recurrence of the noncompliance. We appreciate having been informed about this matter and find no cause for further action by this Office.

Sincerely,

Axel Wolff, M.S., D.V.M.

Deputy Director

Office of Laboratory Animal Welfare

agel Wolfins, Di

cc: IACUC Chair

Office of Research Compliance

Division of Research

PO Box 6000 Binghamton, New York 13902-6000 607-777-4664

A3100-1I

September 15, 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** and PHS Policy IV.F3, is reporting an incident of noncompliance associated with NIAAA funding award number R01AA025784-01. This incident involved mice and the conduct of activity without appropriate IACUC review and approval. No animals were injured as a result of this conduct.

An individual in a Pl's lab was discovered performing intragastric administration of ethanol or water in adolescent and adult mice without IACUC approval. The Pl's lab was approved to do the procedure in rats but not mice. The Pl had given her lab member permission to perform the procedure as she initially believed she had approval in place. When the Pl realized this error, she immediately submitted an amendment. However, there was an apparent lapse in communication by the Pl to lab member to discontinue performing the procedure with mice until approval. Upon discovery by the Attending Veterinarian of the continued non-compliance, the Pl and the lab member were told to stop the procedures and wait for IACUC approval. The Pl and the lab member complied with that directive.

The IACUC chairman spoke to the PI about this issue of non-compliance to ensure her understanding of the relative policies and procedures to which all are to abide. The PI was apologetic, understood her error in proper communication and that amendments require approval before such work is started. She agreed that to prevent such incidents in the future, she and her lab personnel will review her approved protocols before performing a procedure to ensure approval of such a procedure.

Please feel free to contact me should you have any questions (nlewis@binghamton.edu).

Sincerely,

Nancy L. Lewis

Assistant Vice President for Research Compliance

Institutional Official

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c: 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:

Monday, September 18, 2017 9:28 AM

To:

'Nancy L Lewis'

Subject:

RE: Binghamton University-noncompliance report

Thank you very much, it came through fine.

Axel Wolff

From: Nancy L Lewis [mailto:nlewis@binghamton.edu]

Sent: Monday, September 18, 2017 8:07 AM

To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>

Subject: RE: Binghamton University-noncompliance report

My sincere apologies Dr. Wolff.

Respectfully,

Nancy Lewis
Assistant Vice President for Research Compliance
Binghamton University
Ph. Phone Number
Fax. Phone Number
nlewis@binghamton.edu

From: OLAW Division of Compliance Oversight (NIH/OD) [mailto:olawdco@od.nih.gov]

Sent: Monday, September 18, 2017 7:44 AM To: Nancy L Lewis <nlewis@binghamton.edu>

Subject: RE: Binghamton University-noncompliance report

Please resend this as there was no attachment.

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

From: Nancy L Lewis [mailto:nlewis@binghamton.edu]

Sent: Friday, September 15, 2017 4:12 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.

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

Respectfully,

Nancy Lewis
Assistant Vice President for Research Compliance
Binghamton University
Ph. Phone Number
Fax. Phone Number
nlewis@binghamton.edu