



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 B 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) 480-3387

January 24, 2020

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

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 January 14, 2020 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the Binghamton University.

According to the information provided, this Office understands that Binghamton University determined that instances of noncompliance occurred with respect to: rats not receiving post-operative analgesics as described in the approved protocol. The animals underwent site-specific brain cannulation surgical procedures, recovered well and appeared to be healthy. However, AAALAC site visitors discovered on October 28, 2019 that animals did not receive analgesics (buprenorphine) 12h after the pre-emptive dose per the post-operative record. The PI and research assistant were counseled by the Attending Veterinarian (AV) on October 29, 2019 and agreed to administer the analgesic as documented. On November 15th and 16th, the same surgery was performed on 8 rats by the same PI and research assistant. Again, it was discovered that buprenorphine was not administered as described in the protocol per the post-operative records. The letter indicates that the animals recovered well and appeared healthy. Again, the PI and assistant were counseled on the importance of post-operative pain management and strict adherence to the approved protocol. The research assistant was encouraged to use an earlier start time for surgery and to perform it on a smaller number of animals in order to be available post-surgery to administer the analgesic. The AV provided information on an alternative analgesic but emphasized that the timing and doses would remain the same. Since the second counseling, the PI and lab have maintained compliance and adherence to the protocol with no further incidents to date. Also, as a reminder to all university researchers conducting surgery, a notification was sent on October 29, 2019 stating analgesics are to be dosed every 8-12h following the pre-emptive dose.

Based on its assessment of this explanation, OLAW understands that the Binghamton University has implemented appropriate measures to correct and prevent recurrences of these problems and is now compliant with provisions of the PHS Policy. The letter does not state if the animal activities are PHS-funded, and OLAW assumes the IACUC is aware of the noncompliance and in agreement with the corrective action of counseling conducted by the AV. We appreciate being informed of these matters and find no cause for further action by this Office.

Sincerely,

(b) (6)

Jacquelyn T. Tubbs, DVM  
Veterinary Medical Officer  
Division of Compliance Oversight  
Office of Laboratory Animal Welfare

cc: IACUC Chair

January 14, 2020

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. These incidents involved rats whose pain and distress was not managed as documented and expected in the approved protocol.

During an AAALAC site visit on 10/28/2019, visitors discovered in the post-operative record that animals did not receive analgesics 12 hours after the pre-emptive dose, as specified in the protocol. The site-specific brain cannulation surgical procedures were initiated on 10/07/2019 and the animals appeared to have recovered well and to be healthy. The PI and research assistant that performed the surgery were spoken to on 10/29/2019 by the Attending Veterinarian and agreed to administer the analgesic as documented.

On 11/15-16/2019, the same surgery was conducted on eight rats over this two-day period by the same PI and research assistant. Buprenorphine was given pre-emptively and was to be given a second time approximately 12 hours later as per the approved protocol. While the animals recovered well and appeared to be healthy, post-operative records indicated the analgesic was given 14 hours post-surgery to some animals and 24 hours post-surgery to others. The importance of managing postoperative pain or discomfort and strict adherence to the approved protocol was discussed with the PI and the research assistant performing the procedure, to which they acknowledged. The researcher assistant was encouraged to start the procedure earlier in the day and to perform it on a smaller number of animals in order to be available post-surgery to administer the analgesic. The PI discussed possibly using an alternative analgesic. The Attending Veterinarian sent the PI additional information on alternative analgesic, however, it was emphasized that the timing for doses remains the same.

It is to be noted that the PI and lab have maintained compliance and adherence to the associated approved protocol with no further incidents to date. In addition, as a reminder to all Binghamton University researchers conducting surgery, a notification was sent on 10/29/2019 stating analgesics are to be dosed every 8-12 hours following the pre-emptive dose.

Please contact me if you have any questions or would like additional information.

Sincerely,

Digitally signed by Nancy Lewis  
Date: 2020.01.14 10:21:35 -05'00'  
Adobe Acrobat DC version: 2015.006.30508

**Nancy L. Lewis**

**Assistant Vice President for Research Compliance/Institutional Official**

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

**Morse, Brent (NIH/OD) [E]**

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Tuesday, January 14, 2020 11:30 AM  
**To:** Nancy L Lewis; OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: Binghamton University-report of noncompliance

Thank you for submitting this report Ms. Lewis. We will send an official response soon.

Best regards, Brent Morse

Brent C. Morse, DVM, DACLAM  
Director  
Division of Compliance Oversight  
Office of Laboratory Animal Welfare  
National Institutes of Health

Please note that this message and any of its attachments are intended for the named recipient(s) only and may contain confidential, protected or privileged information that should not be distributed to unauthorized individuals. If you have received this message in error, please contact the sender.

**From:** Nancy L Lewis [mailto:nlewis@binghamton.edu]  
**Sent:** Tuesday, January 14, 2020 10:27 AM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Subject:** Binghamton University-report of noncompliance

Director,

Binghamton University, in accordance with PHS Assurance #D16-00063, respectfully reports two incidents of noncompliance for failure to adhere to an approved protocol on a non-NIH funded project.

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](mailto:nlewis@binghamton.edu)  
<https://www.binghamton.edu/research/compliance/>