



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

March 12, 2018

Re: Animal Welfare Assurance  
#A3260-01 (OLAW Case R]

Dr. Heidi Aronin  
Senior Vice President and  
Chief Administrative Officer  
SUNY Downstate Medical Center  
450 Clarkson Avenue, MSC#112  
Brooklyn, NY 11203

Dear Dr. Aronin,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your February 26, 2018 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the SUNY Downstate Medical Center. According to the information provided, OLAW understands that five rats on a PHS-funded study did not receive pre-surgical Tylenol in the drinking water as required as part of the analgesia regimen.

Corrective actions included counseling of the PI including review of the noncompliance. The PI will follow the comprehensive analgesia plan as approved in the protocol.

OLAW appreciates the prompt consideration of this matter by the SUNY Downstate Medical Center, which was consistent with the philosophy of institutional self-regulation. Based on the information provided, OLAW is satisfied that appropriate actions have been taken regarding this incident. We appreciate being informed of this matter and find no cause for further action by this office.

Sincerely,

(b) (6)

Brent C. Morse, DVM  
Acting Director  
Division of Compliance Oversight  
Office of Laboratory Animal Welfare

cc: IACUC Contact



University Hospital of Brooklyn  
College of Medicine  
School of Graduate Studies  
School of Public Health  
College of Nursing  
College of Health Related Professions

**Institutional Animal Care and Use Committee**

February 26, 2018

Acting Director, Division of Compliance Oversight  
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

Animal Welfare Assurance Number: D16-00167(A3260-01)

Dear Dr. Morse,

I'm writing to advise you of a protocol non-compliance associated with a PHS-funded project. Between July – September 2017, five rats underwent survival surgery and received multimodal intra- and post-operative analgesia as described in the protocol. However, provision of Tylenol-medicated water was not initiated 48-hours prior to surgery according as approved. The Attending Veterinarian and Director, Office of Animal Welfare met with the PI to review the non-compliance, and the PI will follow the comprehensive analgesia plan as approved in the protocol. During the preliminary verbal report of the non-compliance to OLAW, we were advised that the amount of animal-related costs is below the threshold for reimbursement to the NIH. Please let us know if you need additional information on this matter.

Best,

(b) (6)

Heidi Aronin  
Institutional Official

**Wolff, Axel (NIH/OD) [E]**

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Wednesday, February 28, 2018 7:21 AM  
**To:** (b) (6)  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: Non-compliance Report (D16-00167/A3260-01)

Thank you for this report, (b) (6) We will respond soon. This electronic mailbox is the correct one to submit all final noncompliance reports.

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

**From:** (b) (6)@downstate.edu]  
**Sent:** Tuesday, February 27, 2018 5:03 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Subject:** FW: Non-compliance Report (D16-00167/A3260-01)

Per Dr. Morse's out of office reply, this is being forwarded for review. Please let me know if there are additional questions or clarifications.

Best,

(b) (6)

**From:** (b) (6)  
**Sent:** Tuesday, February 27, 2018 4:53 PM  
**To:** Brent Morse (morseb@mail.nih.gov) <morseb@mail.nih.gov>  
**Cc:** Heidi Aronin (Heidi.Aronin@downstate.edu) <Heidi.Aronin@downstate.edu>  
**Subject:** Non-compliance Report (D16-00167/A3260-01)

Dear Dr. Morse,

Please find our written report of a non-compliance related to the initial verbal report made on January 19, 2018. Please let us know if you have any additional questions or clarifications.

Best,

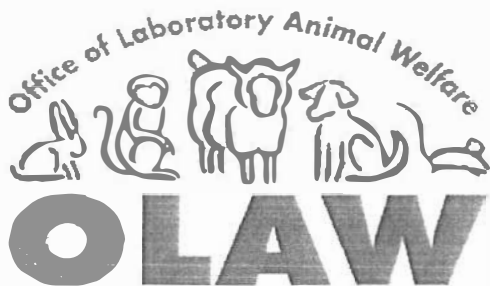
(b) (6)

(b) (6)



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## Initial Report of Noncompliance

By: *[Signature]*

Date: 1/19/18

Time: 3:35

Name of Person reporting: [Redacted] (b) (6)

Telephone #: [Redacted] (b) (6)

Fax #: [Redacted]

Email: [Redacted]

Name of Institution: SUNY - Downstate

Assurance number: A3260

Did incident involve PHS funded activity? \_\_\_\_\_

Funding component: \_\_\_\_\_

Was funding component contacted (if necessary): \_\_\_\_\_

What happened?

5 rats did not receive tylenol in water before surgery as required by protocol

Species involved: Rat

Personnel involved: Researcher

Dates and times: \_\_\_\_\_

Animal deaths: \_\_\_\_\_

Projected plan and schedule for correction/prevention (if known): \_\_\_\_\_

Projected submission to OLAW of final report from Institutional Official: \_\_\_\_\_

OFFICE USE ONLY

Case # \_\_\_\_\_