



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

January 15, 2019

Re: Animal Welfare Assurance  
A3222-01 [OLAW Case Q]

Aleister Saunders, Ph.D.  
Senior Vice Provost for Research  
Drexel University  
3180 Chestnut Street, (b) (4)  
Philadelphia, PA 19104

Dear Dr. Saunders,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your December 12, 2018 letter reporting several instances of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Drexel University, following up on an initial telephone report on November 19, 2018. According to the information provided, OLAW understands that the Institutional Animal Care and Use Committee (IACUC) identified six laboratories with expired analgesics/anesthetics or containers with labels with no expiration date. The drug containers were mingled with in-date drugs. One laboratory was supported by NSF grant #1751898.

The corrective actions consisted of removing the expired agents. A new policy was implemented whereby expired or improperly labeled analgesics/anesthetics will result in the Principal Investigator submitting quarterly inventory reports of such drugs to the IACUC.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to address this problem. While OLAW concurs with the actions taken thus far by the IACUC to comply with the PHS Policy, this remedy could still lead to use of expired analgesics/anesthetics with potential negative animal welfare effects. Other institutions facing a similar problem have instituted color coded marking systems and appointing a laboratory member to check expiration dates monthly. Some institutions maintain an electronic inventory which is checked monthly to allow timely removal of expired drugs. Ongoing violations have resulted in personnel actions for the individuals responsible for monitoring and placing the laboratory on direct enhanced post-approval monitoring by the IACUC. Please inform OLAW if the noncompliance persists and/or if additional measures have been taken to prevent recurrence. Thank you for keeping OLAW apprised on this matter.

Sincerely,

(b) (6)

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

cc: IACUC Chair  
NSF Animal Welfare Officer



December 12, 2018

Axel Wolff, DVM  
Director, Division of Compliance Oversight  
Office of Laboratory Animal Welfare  
National Institutes of Health  
Rockledge 1, Suite 360  
6705 Rockledge Drive  
Bethesda, MD 20892

Dear Dr. Wolff:

Drexel University, in accordance with Assurance D16-00138 and PHS Policy IV.F.3., provides this report of noncompliance of analgesic and anesthetic drugs found in working stock during IACUC semi-annual inspections which had expired or lacked a clear expiration date. Five out of the six individual laboratories which were identified are currently supported with PHS and NSF funding. The work performed is supported by NIH grant award numbers AI136716-01, 4U01HL116556-04, 5R01MH85666, 152732/R01NS041596, and NSF award number 1751898.

During the fall 2018 IACUC semi-annual inspections, six individual laboratories contained one or more anesthetic or analgesic drugs which had either expired or did not have a clear expiration date label. These expired or unlabeled anesthetics or analgesics were located within working drug stock.

Each instance was identified as a significant deficiency and required removal of the noted drug from working stock within 24 hours. In two laboratories, the investigators removed the drugs at the time of the inspection. In the remaining laboratories, the Principal Investigator responded to a written notification and stated that the drugs had been removed from the working stock within the required time.

On 11/14/2018, a subset of the IACUC met to conduct the semi-annual program review and determined that though procedures were in place to ensure analgesics and anesthetics are used within the expiration date, the current program needed to be improved. A regularly convened IACUC meeting occurred subsequent to the program review. During the meeting, the IACUC discussed the current analgesic and anesthetic monitoring program and voted to approve the following plan of action:

- The Office of Research will notify OLAW of the deficiencies related to expired analgesics and anesthetics found during the fall 2018 semi-annual inspections.

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IACUC@drexel.edu | [drexel.edu/research](http://drexel.edu/research)



- A new policy will be established where, if expired or improperly labeled anesthetic or analgesic drugs are found during an announced inspection, the Principal Investigator must submit quarterly inventory reports of all anesthetic and analgesic drug stock to the IACUC for a minimum of one year. The quarterly report policy will apply to the laboratories identified during the fall 2018 semi-annual inspections. The IACUC chair will inform all Principal Investigators of the violation and this new policy.
- The IACUC chair will notify those Principle Investigators which had expired or missing expiration labels of anesthetic or analgesic drugs found during the fall 2018 semi-annual inspections and inform them of the above policy. The chair will also reinforce the severity of using expired analgesic and anesthetics.

Drexel University is committed to protecting the welfare of animals used in research and appreciates the guidance and assistance provided by OLAW in this regard. Should you have any questions regarding this report, please contact Michael O'Connor, MD, PhD, IACUC Chair or Richard Huneke, DVM, attending veterinarian.

Thank you for your consideration of this matter.

(b) (6)

Aleister Saunders, Ph.D.  
Senior Vice Provost for Research  
Institutional Official

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

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Monday, January 14, 2019 5:07 PM  
**To:** Iacuc; OLAW Division of Compliance Oversight (NIH/OD)  
**Cc:** (b) (6) Saunders, Aleister  
**Subject:** RE: Reports of Non-Compliance, Adverse Event - Drexel University- D16-00138

Thank you for submitting these reports. We will send official responses soon.

Best regards, Brent Morse

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

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**From:** Iacuc <iacuc@drexel.edu>  
**Sent:** Monday, January 14, 2019 3:43 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Cc:** (b) (6) Saunders, Aleister <ajs56@drexel.edu>  
**Subject:** Reports of Non-Compliance, Adverse Event - Drexel University- D16-00138

Good Afternoon,

Please find attached two final reports of noncompliance and one final adverse event report to the Office of Laboratory Welfare. Initial reports were made by phone on 11/19. Please let me know if you need any additional information.

Sincerely,

(b) (6)

(b) (6)



## Initial Report of Noncompliance

By: Neera Gopee

Date: 11-19-18

Time: 2:16pm

Name of Person reporting: (b) (6) and IACUC Chair  
 Telephone #: (b) (6)  
 Fax #:  
 Email:

Name of Institution: Drexel University  
 Assurance number: A3222-01

Did incident involve PHS funded activity? Yes / Partially  
 Funding component: \_\_\_\_\_  
 Was funding component contacted (if necessary): \_\_\_\_\_

(15-2732 R01 NS041596  
 44 01HL11 655604  
 5 R01M HP 566  
 NSF 1751898

What happened?

- identified exposed or undetected anesthetic and analgesics in 6 different  
lots at commercial inspection

Species involved:

Personnel involved: Research personnel

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 # \_\_\_\_\_