



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

December 26, 2018

Re: Animal Welfare Assurance  
#A3348-01 (OLAW Case 1Y)

Thomas F. Murray, Ph.D.  
Provost  
Creighton University  
2500 California Plaza  
Omaha, NE 68178

Dear Dr. Murray,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your December 13, 2018 letter regarding noncompliance with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (Policy) at Creighton University. This letter was preceded by a preliminary report to OLAW via telephone on November 26, 2018. According to the information supplied, OLAW understands that during the semiannual inspections in August 2018, analytic grade xylazine was discovered during laboratory inspections without an expiration date on the bottle. Over an extended period of time, the analytic grade xylazine was used by a laboratory in a ketamine/xylazine cocktail for several mice. The letter indicated that the associated animal activities were not PHS funded.

The corrective actions included the principal investigator (PI) immediately discontinuing use of the xylazine and subsequently providing the IACUC with verification of the purchase of new pharmaceutical grade xylazine.

Based on the information provided, OLAW concurs with the actions taken by the institution and IACUC to adhere to the PHS Policy. OLAW assumes that re-training and/or counseling was provided to educate the PI and laboratory members on the rationale for use of pharmaceutical grade agents and the importance of administration of agents that are appropriate for use in animals including agents that are within their expiration date. Although the involved animal activities were not PHS funded, the application of the standards of the PHS Policy across the animal care and use program reduces any potential appearance of a double standard. We appreciate being informed of these matters and find no cause for further action by this Office.

Sincerely,

(b) (6)

(b) (6)

Jane Na, DVM  
Veterinary Medical Officer  
Office of Laboratory Animal Welfare

cc: IACUC Chair

# Creighton UNIVERSITY

Office of the Provost  
Research Compliance

December 13, 2018

Dr. Brent Morse  
Office of Laboratory Animal Welfare  
National Institutes of Health  
Division of Compliance Oversight  
6705 Rockledge Drive  
RKL1, Suite 1050, MSC 7982  
Bethesda, Maryland 20892-7982

Re: Creighton's Institutional Animal Care and Use Committee (IACUC) Animal Incident Report,  
Assurance Number A3348-01/D16-00226

Dear Dr. Morse:

Creighton University is submitting a finalized report regarding a protocol violation that was initially reported to you via phone on November 26, 2018 by the Research Compliance Auditor.

**Background Information/Protocol Violation Issue:**

During the IACUC semi-annual inspections in August of 2018, an analytical grade Xylazine was discovered during laboratory inspections. Upon further investigation, it was discovered that the analytical grade Xylazine which was labelled "not for human or animal use" and did not contain an expiration date on the bottle. This had been used to make an anesthetic ketamine/xylazine cocktail for several mice over an extended period of time.

**Corrective Action Plan Taken:**

The following corrective action plan was formulated by a subcommittee of the IACUC and carried out by the PI:

- The PI immediately discontinued the use of the Xylazine and the bottle was confiscated by the IACUC and appropriately disposed.
- The PI provided the IACUC with verification that a new pharmaceutical grade Xylazine was purchased for future procedures.

**Reporting:**

The following agencies/organizations will be contacted regarding this noncompliance:

- The Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC) will be informed of this noncompliance.
- No additional reporting is required as this protocol was not Public Health Service (PHS) funded.

Please feel free to contact Dr. Thomas F. Murray, Provost and Institutional Official, at (b) (6), or Dr. Joseph A. Knezetic, Director of Research Compliance, at (b) (6) if you have any further questions.

Sincerely,

(b) (6)

Thomas F. Murray Ph.D.  
Institutional Official and  
Provost

(b) (6)

Joseph A. Knezetic, Ph.D.  
Director of Research Compliance

CC: IACUC Chair  
Animal Resource Facility Director  
Research Compliance Office

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

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Thursday, December 20, 2018 3:22 PM  
**To:** (b) (6) OLAW Division of Compliance Oversight (NIH/OD)  
**Cc:** Murray, Thomas F; Knezetic, Joseph A; (b) (6)  
**Subject:** RE: Creighton University -- 3 OLAW Reports

Thank you for providing these reports (b) (6) We will send official responses soon.

Best regards, Brent Morse

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

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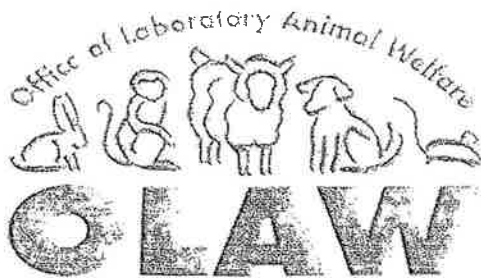
**From:** (b) (6)  
**Sent:** Thursday, December 20, 2018 3:01 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Cc:** Murray, Thomas F <tfmurray@creighton.edu>; Knezetic, Joseph A <joek@creighton.edu>; (b) (6)  
(b) (6)  
**Subject:** Creighton University -- 3 OLAW Reports

Please find attached 3 separate finalized written reports regarding incidents reported to you via phone November 26, 2018.

Thank You,  
(b) (6)

(b) (6)





## Initial Report of Noncompliance

By: BMMDate: 11/27/18Time: 9:25

Name of Person reporting: (b) (6)

Telephone #: (b) (6)

Fax #:

Email:

Name of Institution: Creighton Univ.Assurance number: A33480Did incident involve PHS funded activity? ?

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

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

What happened?

Non-pharm. grade Xylazine used  
for Ket/Xyl. anesth. (Analytical grade)

Species involved: micePersonnel involved: PIDates and times: August 2018

Animal deaths:

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

Replaced w/ Pharm. grade Xylazine

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY

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