



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

June 19, 2019

Re: Animal Welfare Assurance
#3348-01 (OLAW Case 2D)

Dr. Thomas F. Murray
Provost and Institutional Official
Creighton University
2500 California Plaza
Omaha, NE 68178

Dear Dr. Murray,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your June 5, 2019 letter reporting an instance of noncompliance with a protocol and the PHS Policy on Humane Care and Use of Laboratory Animals at Creighton University. This issue was reported to our office by phone on April 18, 2019. According to the information provided, OLAW understands that on April 4, 2019 one mouse on a research project was found dead in its cage after receiving a bleomycin treatment on March 31st. It was subsequently determined that an incorrect dose of bleomycin was administered to 20 mice. One additional mouse died and the remaining 18 mice were euthanized to prevent future pain and distress. The activity to which the mice were assigned is not funded by the PHS.

Corrective actions included the PI and Attending Veterinarian reviewing together the correct dosage and solution of the compound. Once animal work is resumed, the Research Compliance Auditor will monitor the preparation and administration of the solution.

The prompt consideration of this matter by Creighton University was consistent with the philosophy of institutional self-regulation. Similarly, the actions taken to resolve the issue and prevent recurrence were appropriate. Although this activity was 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 this matter and find no cause for further action by this office.

Sincerely,

(b) (6)

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

cc: IACUC contact

Creighton UNIVERSITY

Office of the Provost
Research Compliance

June 5, 2019

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 April 18, 2019 by the Research Compliance Auditor.

Background Information/Protocol Violation:

On April 4, 2019 one dead mouse was found in its home cage following a bleomycin treatment on March 31st, 2019. Upon discovery, the Attending Veterinarian (AV) performed a post-mortem examination which showed signs of significant edema and gross pathological changes in the lung tissue. Prior to the mortality, the PI also noted unusually high PenH reading during the pulmonary function test. Upon further review of the protocol by the PI, in conjunction with the AV, it was determined that an incorrect dose of bleomycin was administered to 20 mice (1.5 units/mouse instead of 1.5 units/kg). With one dead mouse found in its home cage and one additional that died during oral administration, the remaining 18 mice were humanely euthanized per veterinary directive to prevent any future pain and distress.

Corrective Action Plan Taken:

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

- The AV and the PI reviewed together the correct dosage and solution of the compound.
- Once the PI is ready to resume animal work the preparation of solution and administration will be monitored by the Research Compliance Auditor.

Reporting:

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

- The Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC).
- No additional reporting is required as this is not a PHS funded project.

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]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Thursday, June 13, 2019 7:31 AM
To: (b) (6) OLAW Division of Compliance Oversight (NIH/OD)
Cc: Murray, Thomas F; Knezetic, Joseph A; (b) (6)
Subject: RE: Creighton University -- OLAW Letter

Thank you for providing these final 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: Wednesday, June 12, 2019 12:11 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)
Subject: Creighton University -- OLAW Letter

Dr. Morse-

Attached you will find 2 finalized reports regarding 2 separate incidents, both initially reported to you via phone April 18, 2018.

Thank You,

(b) (6)

(b) (6)





Initial Report of Noncompliance

By: rgmDate: 4/18/19Time: 4:00

Name of Person reporting: (b) (6)

Telephone #: (b) (6)

Fax #:

Email:

Name of Institution: Creighton U.Assurance number: A33480Did incident involve PHS funded activity? No

Funding component: _____

Was funding component contacted (if necessary): _____

What happened? Incorrect dose administered, 2 mice died. 18 euthanizedSpecies involved: mousePersonnel involved: ResearcherDates and times: 4/4/19

Animal deaths:

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

Counseling.
halted procedures
↑ PAM monitoring

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY

Case # _____