

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

December 26, 2018

PUBLIC HEALTH SERVICE NATIONAL INSTITUTES OF HEALTH

FOR EXPRESS MAIL: Office of Laboratory Animal Welfare 6700B Rockledge Drive, Suite 2500 Bethesda, Maryland 20817 <u>Telephone</u>: (301) 496-7163 <u>Facsimile</u>: (301) 402-7065

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

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, non-pharmaceutical grade MS-222 was discovered during laboratory inspections, but the associated protocol was only approved for pharmaceutical grade MS-222. The principal investigator (PI) confirmed that the non-pharmaceutical grade agent was used over an extended period of time to euthanize approximately 153 zebrafish. The letter indicated that the associated animal activities were not PHS funded.

The corrective actions included the PI immediately discontinuing use of the non-pharmaceutical grade MS-222 and subsequently providing the IACUC with verification of the purchase of pharmaceutical grade MS-222.

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 following the IACUC-approved protocol. 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

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, a non-pharmaceutical grade MS-222 (ethyl 3-aminobenzoate methanesulfonate) was discovered during laboratory inspections. A review of the Investigator's IACUC approved protocols identified that pharmaceutical grade MS-222 was approved for euthanasia. Following confirmation from the PI, it was revealed the non-pharmaceutical drug had been used over an extended period of time to euthanize approximately 153 zebrafish. Additionally, it was verified that the PI followed the AVMA guidelines for use of MS-222 as an euthanasia agent and physical verification of death.

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 used of the non-pharmaceutical grade MS-222 and disposed of the bottle.
- The PI provided the IACUC with verification that a pharmaceutical grade MS-222 was purchased for future procedures.

creighton.edu creighton.edu/researchservices 3348-12

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,

) (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, December 20, 2018 3:22 PM	
То:	(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

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:^{(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)}

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)



A3348-12 effect of Loboratory Animal Well Initial Report of Noncompliance By: Date: \\ / Time (b) (6) Name of Person reporting: Telephone #: (b) (6) Fax #: Email: Univ, Irelation Name of Institution: Assurance number: Did incident involve PHS funded activity? _? Funding component: Was funding component contacted (if necessary): t, 153 zebrafish had been non-phorm. MS222 What happened? On S. Species involved: Danio rerio Personnel involved: Dates and times: A 1-2018 Animal deaths: Projected plan and schedule for correction/prevention (if known): _ grade MS222

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY Case #