

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

May 9, 2019

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

Re: Animal Welfare Assurance #A3165-01 [OLAW Case 1D]

Dr. James J. Tomasek
Vice President for Research and
Dean of Graduate College
University of Oklahoma Health Sciences Center
1000 Stranton L. Young Blvd., Room (b) (4)
Oklahoma City, OK 73111

Dear Dr. Tomasek,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your May 2, 2019 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals within the animal care and use program at the University of Oklahoma Health Sciences Center. According to the information provided, OLAW understands that on March 25, 2019 a research associate was observed not following approved practices while euthanizing mice with CO2. The associate and the PI were counseled by a veterinarian and the IACUC was informed of the incident. The PI requested training for himself and his associate and for the Attending Veterinarian to observe the next ten euthanasia sessions. These animals were not supported with PHS funds.

Corrective and preventive actions included the retraining and observation by the Attending Veterinarian of the demonstrated ability. In addition, the PI committed to: euthanizing mice in their home cage whenever possible, or with animals from their home cage; confirming death with a secondary physical method; use of the approved CO2 displacement rate, and; use of a physical method of euthanasia on neonatal mice. Comparative Medicine will also conduct unannounced follow-up sessions in the PI's facility.

The prompt consideration of this matter by the University of Oklahoma Health Sciences Center was consistent with the philosophy of institutional self-regulation. OLAW concurs that the incident warranted reporting. 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. Based on the information provided, OLAW is satisfied that appropriate actions have been taken to investigate this incident, make corrections, and prevent recurrence. 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



The University of Oklahoma Health Sciences Center

OFFICE OF THE VICE PRESIDENT FOR RESEARCH

May 2, 2019

Brent Morse, DVM
Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
RKL 1, Suite 360, MSC 7982
6705 Rockledge Drive
Bethesda, MD 20892
morseb@od.nih.gov
olawdco@mail.nih.gov

Dear Dr. Morse:

The University of Oklahoma Health Sciences Center (OUHSC), in accordance with Assurance D16-00104 and PHS Policy IV.F.3., provides this final report of an incident that my designee reported to you on April 23, 2019, involving a non-PHS funded project. The University's final report is as follows:

On March 25, 2019, animal care staff observed a research associate not following the IACUC's approved practices while euthanizing mice with carbon dioxide. The animal care staff promptly reported the incident to the attending veterinarian. The veterinarian reminded the PI and the research associate of the expectations for performing this method of euthanasia in accordance with IACUC policy and the AVMA Guidelines for the Euthanasia of Animals. The veterinarian advised the IACUC of this issue shortly thereafter.

On March 29, 2019, after consulting with members of the IACUC, the PI requested formal retraining for himself and his research associate from the attending veterinarian. The PI also volunteered to coordinate the next ten euthanasia sessions in the facility with direct oversight from the attending veterinarian or her designee. Following the formal retraining session and in consultation with the veterinarian, the PI committed to the following:

- 1) Mice will be euthanized in their home cage whenever possible, or with animals from their home cage.
- 2) All mice must undergo a secondary physical method following euthanasia to confirm death.
- 3) The euthanasia station will be used in accordance with IACUC policy; that is, the room air in the chamber will be displaced over time with 10-30% CO₂.
- 4) Neonatal mice are resistant to hypoxia, and thus a physical method of euthanasia is preferable instead of CO₂ asphyxiation. Any changes to the euthanasia method as

865 Research Parkway, Suite 450 Oklahoma City, Oklahoma 73104 · Phone: (405) 271-1083 · Fax: (405) 271-8655 Brent Morse, DVM May 6, 2019 Page 2

described in the approved animal use protocol must first be reviewed and approved by the IACUC.

During its general Committee meeting on April 10, 2019, the IACUC reviewed a summary of the events and remediation plan proposed by the PI. The attending veterinarian informed the IACUC when the ten supervised euthanasia sessions were complete and of her assessment that the PI and his associate demonstrated proper euthanasia procedures on mice undergoing CO₂ asphyxiation. In addition to the remediation plan proposed and completed by the PI, the IACUC also asked Comparative Medicine to perform unannounced follow-up session in the PI's facility to help ensure strict adherence to appropriate euthanasia methods. Comparative Medicine anticipates that these unannounced sessions will begin after June 1.

The University is committed to protecting the welfare of animals used in research and appreciates the guidance and assistance provided by OLAW in this regard. If you have any questions regarding this report or the IACUC's actions, please contact me at the number below or Eric Howard, PhD, IACUC Chair, at Eric-Howard@ouhsc.edu.

Thank you for your consideration of this matter.

Sincerely, (b) (6)

James Tomasek, PhD Vice President for Research Institutional Official The University of Oklahoma Health Sciences Center

CC: Eric Howard, PhD, IACUC Chair
Ron Banks, DVM, Director of the Division of Comparative Medicine
Sandra Nettleton, Director of Compliance

Morse, Brent (NIH/OD) [E]

From:

OLAW Division of Compliance Oversight (NIH/OD)

Sent:

Thursday, May 02, 2019 9:49 AM

To:

Budda, Madeline L (HSC); OLAW Division of Compliance Oversight (NIH/OD)

Cc:

Tomasek, James J. (HSC); Howard, Eric W. (HSC); Banks, Ron E (HSC); Nettleton, Sandra L

(HSC); (b) (6)

Subject:

RE: Final Report

Thank you for this report Dr. Budda. We will send an official response 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: Budda, Madeline L (HSC) [mailto:Madeline-Budda@ouhsc.edu]

Sent: Thursday, May 02, 2019 9:37 AM

To: Morse, Brent (NIH/OD) [E] <morseb@mail.nih.gov>; OLAW Division of Compliance Oversight (NIH/OD)

<olawdco@od.nih.gov>

Cc: Tomasek, James J. (HSC) <James-Tomasek@ouhsc.edu>; Howard, Eric W. (HSC) <Eric-Howard@ouhsc.edu>; Banks,

Ron E (HSC) <Ron-Banks@ouhsc.edu>; Nettleton, Sandra L (HSC) <Sandra-Nettleton@ouhsc.edu>; (b) (6)

(b) (6)

Subject: Final Report

Dear Dr. Morse,

Please see the attached report to follow up on our phone conversation earlier this week.

Regards,

Madeline

Madeline L Budda, DVM, MS, DACLAM
Director, Office of Animal Welfare Assurance
University of Oklahoma Health Sciences Center
Madeline-Budda@ouhsc.edu
(b) (6)

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Initial Report of Noncompliance

Date: 4/29/19 Name of Person reporting: Madeline Budda DVM Telephone #: [60/160] Fax #: Email: Name of Institution: Assurance number: A3165 Did incident involve PHS funded activity? Funding component: Was funding component contacted (if necessary): What happened? No 2 method confirmed of the CO3 for adults. Also about 12 purple were not completely enthanged, found alive in logs. Species involved: Personnel involved: Personnel involved: Researche Personnel involved: Researche Personnel involved: Researche Personnel involved: Pe	OLAW	By:
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Funding component: Was funding component contacted (if necessary): What happened? No 2 method confirmed after CO3 for adults. Also about 12 purple were not Species involved: three personnel involved: Researche 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	Name of Institution: Assurance number: Assurance number:	-SC
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Projected submission to OLAW of final report from Institutional Official: OFFICE USE ONLY	*	
OFFICE USE ONLY	Projected plan and schedule for correction/prevention	on (if known):
OFFICE USE ONLY		
	Projected submission to OLAW of final report from	n Institutional Official: