



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 6, 2020

Re: Animal Welfare Assurance  
#A3237-01 (OLAW Case 3D)

Ms. Steffani Webb  
Vice Chancellor for Administration  
Institutional Official  
University of Kansas Medical Center  
3901 Rainbow Road, MS 2015  
Kansas City, KS 66160

Dear Ms. Webb,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your December 18, 2019 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of Kansas Medical Center.

According to the information provided, this Office understands that the University of Kansas Medical Center Animal Care and Use Committee (ACUC) determined that instances of noncompliance occurred with respect to: lab staff conducting a methamphetamine dosing experiment in a rat on September 5, 2019 without notifying animal care staff and without posting proper signage. This finding was discovered by Laboratory Animal Resources (LAR) veterinary staff on October 4, 2019 while performing routine clinical care and management duties. The final report states notifying animal care staff is required per the institutional policy regarding animal experimentation involving hazards. Proper door signage regarding hazard management as well as cage identification for proper handling/disposal of contaminated waste was posted on October 7, 2019. After the veterinary staff consulted with a toxicologist, it was advised to use a biosafety cabinet rather than cage change station moving forward. It is noted that this research is supported by internal funds.

This information was presented to the convened IACUC on October 15, 2019. The committee determined that the actions taken by LAR staff regarding personnel and occupational health were appropriate. The committee mandated that the PI and research staff meet with the IACUC Chair and Director of Regulatory Affairs Support to emphasize the seriousness of this event. The PI also agreed to include the date of hazards communication to the LAR on animal dosing records moving forward. Additionally, the IACUC required that research staff undergo focused retraining regarding proper hazards communication, and that the PI's departmental chair be notified of this event and its resolution. The committee further voted unanimously to report this incident of noncompliance.

Based on its assessment of this explanation, OLAW understands that the University of Kansas Medical Center has implemented appropriate measures to correct and prevent recurrences of these problems and is now compliant with provisions of the PHS Policy. 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 these matters and find no cause for further action by this Office.

Page 2 – Ms. Webb  
January 6, 2020  
OLAW Case A3237-3D

Sincerely,

(b) (6)

Jacquelyn T. Tubbs, DVM  
Veterinary Medical Officer  
Division of Compliance Oversight  
Office of Laboratory Animal Welfare

cc: IACUC Contact

December 18, 2019

Brent Morse, DVM  
Director, Division of Compliance Oversight  
Office of Laboratory Animal Welfare  
Rockledge One, Suite 360  
6705 Rockledge Drive – MSC 7982  
Bethesda, MD 20892-7982

**Regarding:** University of Kansas Medical Center -- Assurance #A3237-01

**Research Project:** Methamphetamine and Pulmonary Arterial Hypertension  
IACUC Number: 2019-2513

**Funding Agency:** Internal Funds

Dear Dr. Morse:

In accordance with PHS Policy IVF.3b and internal policy, the University of Kansas Medical Center (KUMC) Institutional Animal Care and Use Committee (IACUC) is reporting a deviation from the provisions of the *Guide* as well as our institutional policies and SOPs.

On Friday, 10/4/19 while performing routine clinical care and management duties, Laboratory Animal Resources (LAR) veterinary staff realized that lab staff had initiated a rat methamphetamine dosing experiment on 9/5/19 without notifying animal care staff as required by institutional policy regarding animal experimentation involving hazards. Specifically, 5 rats began receiving 4 daily ip injections of 20 mg/kg methamphetamine for a duration of 5 weeks as approved in ACUP 2019-2513. On Monday, 10/7/19, proper door signage regarding hazard management was subsequently posted as well as cage identification for proper handling/disposal of contaminated waste.

**Specific Corrective Action:**

Upon discovery of the issue, veterinary staff consulted with a board-certified toxicologist who serves our IACUC in an advisory capacity. Handling of animals treated with amphetamine at this dosage and frequency was discussed. He advised the use of a biosafety cabinet rather than cage change station moving forward. In addition, our IACUC director reviewed a paper by Given et al (J Analyt. Tox., 30, 2006) which concluded that methamphetamine was detectable at low levels (avg. 48 ng/mL) in the urine of drug dog detection trainers who routinely handle 500g quantities of methamphetamine during the assembly of training aids. Potentially affected animal caregiver and cagewash staff were notified of the possible exposure and informed of their right

Brent Morse, DVM  
December 18, 2019  
Page Two

to seek medical care at our institution's Occupational Health department. The staff reported no health issues during the exposure period.

**IACUC and Regulatory Affairs for Biological Sciences (RABS) Action:**

This information was presented to the convened IACUC on 10/15/19. The IACUC determined that the actions taken by LAR staff regarding personnel and occupational health were appropriate and further mandated that the PI and research staff meet with the IACUC Chair and Director of Regulatory Affairs Support to emphasize the seriousness of this event and review potential consequences for continued noncompliance. During this meeting, which occurred on 10/30/19, the PI also agreed to include the date of hazards communication to the LAR on animal dosing records moving forward as a simple administrative control to help prevent recurrence.

Additionally, the IACUC required that research staff undergo focused retraining regarding proper hazards communication, which occurred on 11/8/2019, and that the PI's departmental chair be notified of this event and its resolution.

The IACUC further voted unanimously to report this incident of noncompliance to the relevant regulatory and accrediting agencies. This information is also being provided to the Association for the Accreditation of Laboratory Animal Care (AAALAC).

The IACUC and RABS office, in conjunction with LAR, will continue to stress the importance of proper hazards communications as a necessary component of our Occupational Health and Safety program directed towards protecting animal caregiver and cagewash personnel when hazards are involved in animal experimentation. In addition to providing this information during animal user training and during protocol review, additional avenues of training include research department meetings, Post-Approval Monitoring and/or additional communications through signage and quarterly newsletters. If you have questions or need more information, please feel free to contact me at (b) (6)

Sincerely,

(b) (6)

Steffani Webb  
Vice Chancellor for Administration

cc:

(b) (6)  
Nathan Culley, DVM, DACLAM, Chair, IACUC  
Douglas Brandt, DVM, Executive Director, Laboratory Animal Sciences, Attending Veterinarian

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

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Friday, December 20, 2019 7:24 AM  
**To:** Nathan Culley; OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: Incident Report for the University of Kansas Medical Center A3237-01

Thank you for providing these final reports Dr. Culley. 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:** Nathan Culley [mailto:nculley@kumc.edu]  
**Sent:** Thursday, December 19, 2019 4:45 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Subject:** FW: Incident Report for the University of Kansas Medical Center A3237-01

Dr. Morse,

Please find attached, three (3) animal welfare compliance report letters from the University of Kansas Medical Center (A3237-01). Please let me know if you have any further questions regarding the reports. Have a Happy Holiday!

Regards,

Nathan C Culley, DVM, DACLAM  
IACUC Chair  
Executive Director, Regulatory Affairs for Biological Sciences  
University of Kansas Medical Center  
[nculley@kumc.edu](mailto:nculley@kumc.edu)

(b) (6)