



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

October 2, 2019

Re: Animal Welfare Assurance
#A3237-01 (OLAW Case 2Y)

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 July 10, 2019 letter reporting a deviation from University of Kansas Medical Center institutional policies and SOPs. According to the information provided, OLAW understands that on May 7, 2019, the Office of Research Affairs for Biological Sciences was notified that a vial of ketamine/xylazine mixture had been left unattended in an animal housing room which were returned to the laboratory after the Laboratory Animal Resources personnel secured the vial and notified the laboratory. The letter indicated that the associated animal work was funded by a National Institutes of Health grant.

Although the letter indicates that this incident was a deviation from University of Kansas Medical Center institutional policies and SOPs, it may also be considered a deviation from the *Guide for the Care and Use of Laboratory Animals*. Page 115 of the *Guide* indicates that "All those involved in animal care and use must comply with federal laws and regulations regarding human and veterinary drugs and treatments." This incident was said to have resulted from a miscommunication during training of a new lab member. Corrective actions consisted of retraining. The principal investigator instructed all lab staff that any vials containing scheduled drugs must always remain in custody of lab staff unless properly stored. Laboratory Animal Resources will continue to stress the importance of maintaining custody of scheduled drugs when lab members receive these drugs.

Based on the information provided, OLAW accepts the corrective actions described to reduce the likelihood of recurrence of this noncompliance. We appreciate being informed of these matters and find no cause for further action by this Office at this time.

Sincerely,

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Jane Na, DVM, CPIA
Veterinary Medical Officer, OLAW
National Institutes of Health

cc: IACUC Contact



July 10, 2019

Axel Wolff, MS, 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: HIV/Cocaine mediated human pulmonary vascular remodeling: Role of BMPR signaling
IACUC Number: 2018-2446

Funding Agency: NIH-NAED R01-DA042715

Dear Dr. Wolff:

In accordance with internal policy, the University of Kansas Medical Center (KUMC) Institutional Animal Care and Use Committee (IACUC) is reporting a deviation from our institutional policies and SOPs.

On 05/07/19, the Office of Research Affairs for Biological Sciences (RABS), received a report that a vial of prepared ketamine/xylazine mixture had been found out of custody and unattended the prior day in an animal housing room. Laboratory Animal Resources (LAR) personnel notified laboratory staff associated with the room upon discovery then secured the vial in the LAR drug safe. The following day, the vial was returned to laboratory staff custody.

Specific Corrective Action:

The RABS Director of Research Affairs Support met with the PI and laboratory staff on 05/14/19 and learned that the ketamine/xylazine cocktail had been mistakenly left behind due to a miscommunication during training of a new laboratory member. The PI also stated that all laboratory members have been clearly instructed that any vials containing scheduled drug in any form must remain in custody of laboratory staff at all times until being properly secured. Examination of records and the laboratory drug safe showed that ketamine logs were current and that all primary drug containers were not missing unaccounted volume.

Axel Wolff, MS, DVM
July 10, 2019
Page Two

IACUC and RABS Action:

This information was presented to the convened IACUC on May 21, 2019. The IACUC determined that the lapse in custody of a scheduled drug was appropriately addressed and resolved by the PI. The IACUC further voted unanimously to report this incident 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 maintaining compliance with our institutional policies and SOPs. The importance of maintaining custody of scheduled drugs is emphasized when laboratory members receive these from the LAR. Additional avenues of training include research department meetings, Post-Approval Monitoring reviews and/or additional communications through signage and quarterly newsletters. If you have questions or need more information, please feel free to contact me at

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Sincerely,

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Steffani Webb
Vice Chancellor for Administration

cc:

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

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, July 12, 2019 10:42 AM
To: Nathan Culley
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Incident Report for the University of Kansas Medical Center A3237-01

Thank you for these reports, Dr. Culley. We will send responses soon.
Axel Wolff

From: Nathan Culley <nculley@kumc.edu>
Sent: Friday, July 12, 2019 9:59 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: Incident Report for the University of Kansas Medical Center A3237-01

Dr. Wolff,

Please find attached, three (3) animal welfare compliance report letters from the University of Kansas Medical Center (A3237-01). One report is a little delayed due to our AAALAC site visit in June, I apologize for that. Please let me know if you have any further questions regarding the reports.

Regards,

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

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