



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) 480-3387

July 7, 2020

Re: Animal Welfare Assurance
#A3237-01 (OLAW Case 31)

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 June 19, 2020 letter reporting an incident of noncompliance with the PHS Policy on the Humane Care and Use of Laboratory Animals at the University of Kansas Medical Center. According to the information provided, OLAW understands that on March 9, 2020 four cages of 17 mice were transported from the vivarium by laboratory staff for imaging, contrary to established institutional procedures. An additional two mice were transported before the PI was contacted. The experiment was completed and the study was subsequently discontinued. The animal activity associated with this incident was PHS supported.

Corrective and preventive measures included restricting vivarium access by laboratory personnel and mandating additional Post-Approval Monitoring. An official notification was sent to the PI and departmental chair. Animal biosecurity will be emphasized at training and outreach efforts.

OLAW believes that the corrective and preventive measures put in place by the University of Kansas Medical Center are consistent with the provisions of the PHS Policy on Humane Care and Use of Laboratory Animals for self-monitoring and self-correction. We appreciate being informed of this incident and find no cause for further action by this office.

Sincerely,

Brent C. Morse -S

Digitally signed by Brent C.
Morse -S
Date: 2020.07.07 10:23:50 -04'00'

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

cc: IACUC Contact



June 19, 2020

Brent Morse, DVM, DACLAM
 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: Identification of molecular and cellular basis of the invasive phenotype in human ductal carcinoma in situ
 IACUC Number: 2019-2352

Funding Agency: NIH-NCI R01CA207445

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 Monday, 3/9/20, 4 cages of 17 of mice were transported between vivaria directly by laboratory staff rather than via Laboratory Animal Resources (LAR) SOP. On Wednesday, 3/11/20, LAR veterinary staff advised the PI on the importance of minimizing biosecurity risks by following established procedures, but by that time, an additional 2 mice were also moved without notice or authorization. These immunocompromised, tumor-bearing mice had been enrolled in a pilot study to develop new imaging techniques for tracking tumor growth. Of these 19 animals, 7 underwent imaging procedures from 3/10/20 to 3/11/20. All animals were then removed from study and euthanized from 3/21/20 to 3/22/20. The decision to discontinue this study was made, in part, due to the COVID-19 outbreak and reduction in workforce at KUMC.

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

This information was initially presented by LAR veterinary staff to the convened IACUC on 3/17/20. After discussion, the committee voted to restrict vivarium access of laboratory

Brent Morse, DVM, DACLAM
June 19, 2020
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personnel and mandated additional Post-Approval Monitoring (PAM) and to report back to the IACUC at the next monthly meeting. Upon further discussion by the committee at the convened meeting on 4/21/20, the IACUC voted unanimously to report this issue of noncompliance to the relevant regulatory and accrediting agencies. Additionally, the IACUC determined to send an official notification emphasizing the importance of ensuring animal biosecurity at KUMC vivaria and the potential consequences, including protocol suspension, of continued non-compliance. This notification was sent to the PI and departmental chair on Monday, 5/11/2020. At the convened meeting on 5/19/2020, the IACUC determined that issues had been resolved appropriately with additional PAM oversight per previous discussions.

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 assuring animal biosecurity at KUMC vivaria during animal user training, post-approval monitoring and additional outreach efforts such as elevator signage and quarterly newsletters or institutional "town-hall" events.

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

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, June 24, 2020 7:56 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 this report, Dr. Culley. We will respond soon.

Axel Wolff, M.S., D.V.M.
Deputy Director, OLAW

From: Nathan Culley <nculley@kumc.edu>
Sent: Tuesday, June 23, 2020 12:58 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Iacuc <IACUC@kumc.edu>
Subject: Incident Report for the University of Kansas Medical Center A3237-01

Dr. Morse,

Please find attached, one (1) animal welfare compliance report letter from the University of Kansas Medical Center (A3237-01). Please let me know if you have any further questions regarding the reports. Hope you are staying safe.

Regards,

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

(b) (6)