



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

April 27, 2020

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

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 April 15, 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 January 22, 2020 three mice from a cohort of 12 that had been gavaged were determined to have been injured during the procedure and required euthanasia. The PI determined that two new laboratory members who had been trained to perform gavage by the PI required further training before performing the procedure. This was accomplished and a cohort of eight additional mice recovered from gavage without issue. The animal activity associated with this incident was PHS supported.

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: 2020.04.27 12:40:21 -04'00'

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

cc: IACUC Contact

April 15, 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: Counteracting Molecular Mechanisms of Obesity Dependent
PDAC Progression
IACUC Number: 2019-2493

Funding Agency: NIH-NCI R01-CA231052

Dear Dr. Morse:

In accordance with PHS Policy and our internal policies, the University of Kansas Medical Center (KUMC) Institutional Animal Care and Use Committee (IACUC) is reporting an adverse event associated with the above project.

On Wednesday, 1/22/20, Laboratory Animal Resources (LAR) issued health check notifications for 2 mice presenting with hunch/scruffy appearance and decreased activity. Laboratory staff promptly arrived and identified the animals as members of a cohort of 12 having previously undergone oral gavage procedures. Upon further examination, the PI determined that the two mice as well as an additional mouse also exhibiting minor symptoms were likely injured during oral gavage, and humanely euthanized all 3 animals and an adverse event report was sent to the IACUC.

Specific Corrective Action:

The two new laboratory members had recently been trained by the PI and deemed proficient to perform oral gavage. However, the PI determined that additional retraining and supervision was needed prior to performing any further oral gavage procedures. Such training included, in a stepwise manner, cadaver gavage and exam, live gavage followed by necropsy, experimental gavage under supervision. Following retraining an additional experimental cohort of 8 mice were enrolled in study and all have recovered from oral gavage procedures without incident.

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

This information was originally presented to the convened IACUC on 02/18/2020. After discussion, the IACUC determined that the incident handled appropriately, but requested additional details regarding the numbers of mice affected and oral gavage retraining efforts. At

the following convened IACUC on 3/17/2020 the IACUC determined that no further action was required and voted unanimously to report this adverse event and its resolution 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, in conjunction with the LAR, will continue to help PIs understand the need to report unexpected adverse events associated with their animal research studies. Continuing education related to adverse events and reporting requirements is covered in our Animal User Training with additional avenues associated with Post Approval Monitoring reviews and veterinary assistance in related cases. 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, April 22, 2020 7:17 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 respond soon.
Axel Wolff

From: Nathan Culley <nculley@kumc.edu>
Sent: Monday, April 20, 2020 3:24 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, two (2) 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. 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)