



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 3B)

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 adverse event 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 an adverse event occurred with respect to: 12 genetically modified mice enrolled in a colitis/colon cancer study that were found dead. The final report states that control mice in the same experiment were not lost, indicating a strain-specific sensitivity to AOM treatment. High levels of early mortality following AOM treatment was not predicted as a potential outcome. The PI notified the Office of Regulatory Affairs for Biological Sciences of these unexpected losses on October 3, 2019. The PI stated that experiments involving AOM treatment have been discontinued until an addendum to calculate a dose titration curve is developed and approved. It is noted that this research is PHS funded.

The IACUC was presented the initial report during the October 15, 2019 meeting and requested additional information to make a more informed decision. At the November 19, 2019 IACUC meeting, the committee determined that the matter was resolved appropriately and voted unanimously to report the incident as an adverse event.

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. We appreciate being informed of these matters and find no cause for further action by this Office.

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 Projects: Epigenetics and Infection-induced EMT of Colonic Crypts-
Target for Chemoprevention
IACUC Number: 2017-2425

Funding Agency: NIH-NCI R01CA185322

Dear Dr. Morse:

In accordance with PHS Policy IV.F.3 and OLAW Guidance notice NOT-OD-05-031, 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 September 25, 2019, a cohort of 12 genetically modified mice enrolled in a colitis/colon cancer study were found dead. This was the initial experiment in which these mice were utilized in this well-established disease model induced by Citrobacter infection and subsequent azoxymethane (AOM) treatment. Importantly, control animals enrolled in this same experiment were not lost, thus indicating a strain-specific sensitivity to AOM treatment. Although the ACUP above did hypothesize that these mice would be more prone to develop colon cancer, high levels of early mortality following AOM treatment was not a predicted potential outcome.

Study Specific Corrective Action:

On 10/03/19, the PI notified KUMC's Office of Regulatory Affairs for Biological Sciences (RABS) of these unexpected losses and that experiments involving AOM treatment in this strain of mice have been discontinued until an addendum to calculate a dose titration curve is developed and approved.

Brent Morse, DVM
December 18, 2019
Page Two

IACUC and RABS Action:

The IACUC was presented with an initial report during its regularly convened monthly meeting on 10/15/18. Additional information was requested so that a more informed decision could be made during the following meeting on 11/19/19. At this subsequent meeting the IACUC determined that the matter was resolved appropriately and voted unanimously to report the incident as an adverse event to the relevant regulatory/accreditation agencies. This information is also being reported to the Association for the Assessment and Accreditation of Laboratory Animal Care (AAALAC International).

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]

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

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: 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

(b) (6)