



DEPARTMENT OF HEALTH & HUMAN SERVICES

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Office of Laboratory Animal Welfare  
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FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare  
6700B Rockledge Drive, Suite 2500  
Bethesda, Maryland 20817  
Telephone: (301) 496-7163  
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March 12, 2020

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

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 March 2, 2020 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 (KUMC). This letter had not been preceded by a preliminary report to OLAW.

According to the information provided, this Office understands that the KUMC Animal Care and Use Committee (ACUC) determined that instances of noncompliance occurred with respect to: seven mice found dead and three mice found moribund by Laboratory Animal Resources (LAR) veterinary staff on September 27, 2019. The final report states LAR veterinary staff informed the research staff of the finding and the lab manager arrived and euthanized the remaining moribund animals. Initial discussions between the LAR veterinarian and lab manager revealed that the mice in question were part of an approved survival study in which death following irradiation was the approved experimental endpoint. However, the lab manager failed to mark the cages as previously agreed. Also, the lab manager admitted that when he became ill, he failed to communicate with laboratory or veterinary staff to ensure the animals were monitored as required. Veterinary staff contacted the office of Regulatory Affairs for Biological Sciences (RABS) with this report of mortality and morbidity.

Per the report, on October 8, 2019 RABS staff met with research staff to review the event and associated records, and to discuss the importance of proper communication and animal monitoring in future studies. As a result of the meeting additional deviations were discovered and they included:

- Modifications to experimental timelines and dosing paradigms that were changed without first securing IACUC approval.
- Deficiencies in recordkeeping, especially in terms of adequately documenting animal monitoring per ACUP requirements.

Revisions were made to the ACUP to clarify requirements for monitoring to assure each set of experiments had appropriate parameters defined. The above information was presented to the IACUC on November 18, 2019. The committee determined that lab staff must meet with RABS personnel on a monthly basis to demonstrate compliance with their approved protocols for the next 6 months, and further deficiencies may result in additional remediation including protocol suspension.

The lab's progress was reported to the convened IACUC on December 17, 2019 and again on January 21, 2020. Addenda to modify experimental timelines and dosing strategies as well as those to correct or clarify confusing language in the ACUPs have been submitted and approved. Recordkeeping has been modified to include all procedural and monitoring events and summary coversheets for each experiment have been developed. Lab staff have also received additional body condition scoring and anesthesia training by LAR staff.

Based on the information provided, the Office of Laboratory Animal Welfare (OLAW) is satisfied that appropriate actions have been taken to investigate, correct, and prevent recurrence of the noncompliance. We appreciate being informed of these matters and find no cause for further action by this Office.

Sincerely,

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

cc: IACUC Contact

March 2, 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 Projects:** Inflammation Induced Colon Cancer Related with  
Macrophage and Macrophage Derived Factors  
IACUC Number: 2017-2382

Stromal Cell Therapy for Mitigation of Acute Radiation  
Induce (Gastrointestinal) Syndrome  
IACUC Number: 2019-2487

**Funding Agency:** NIH-NIDDK K01-DK096032

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, 9/27/19, Laboratory Animal Resources (LAR) veterinary staff informed research staff that 7 dead and three moribund mice had been found in housing under ACUP 2019-2487. The lab manager promptly arrived and euthanized the remaining moribund animals.

During initial discussions with the LAR veterinarian, the laboratory manager stated that the mice in question were part of an approved survival study in which death following irradiation was the approved experimental endpoint. However, the lab member in charge of this study failed to mark the cages as such as previously agreed. In addition, the lab manager reported that he was sick and failed to monitor the animals that morning or to communicate with laboratory or veterinary staff to ensure that the animals were monitored as required. Veterinary staff subsequently contacted the office of Regulatory Affairs for Biological Sciences (RABS) with this report of mortality and morbidity.

**Tubbs, Jai (NIH/OD) [E]**

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Friday, March 6, 2020 10:17 AM  
**To:** Nathan Culley; OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: Incident Report for the University of Kansas Medical Center A3237-01

Good morning,

Thank you for the reports. We will send an official response soon.

Kind Regards,

Jacquelyn Tubbs, DVM, DACLAM  
Veterinary Medical Officer  
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 <nculley@kumc.edu>  
**Sent:** Thursday, March 5, 2020 3:43 PM  
**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. 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.

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)

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