



DEPARTMENT OF HEALTH & HUMAN SERVICES

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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

March 16, 2022

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

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 1, 2022 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals within the animal care and use program at the University of Kansas Medical Center. According to the information provided, OLAW understands that, in November and December 2021, there were multiple inventory management issues which led to the unintentional provision of expired feed, shortages of disposable water bottles and shortages of other animal supplies. Issues were reported involving inventory tracking procedures, stock rotation, and product storage deficiencies.

Corrective and preventive measures were enacted to improve inventory management: 1) SOPs have been updated to provide more flexibility and direction regarding expiration dates and proper storage of feed, bedding, and disposable water bottles. 2) New inventory management software has been implemented to facilitate ordering and prevent shortages. 3) Where space allows, working inventory has been relocated apart from supply reserves to control access and help ensure stock rotation. 4) A dedicated husbandry staff member will track inventory weekly and additional staff will provide general feedback regarding inventory levels and expiration. 5) Quality Assurance and Quality Control staff will track and report summary inventory management information to the IACUC monthly.

OLAW appreciates the consideration of this matter by the University of Kansas Medical Center, which was consistent with the philosophy of institutional self-regulation. Based on the information provided, OLAW is satisfied that appropriate actions have been taken to investigate this incident and prevent recurrence. However, in future reports, please state whether the programmatic issue(s) negatively impacted animal welfare.

We appreciate being informed of this matter and find no cause for further action by this office.

Sincerely,

Robyn M. Engel - Digitally signed by Robyn M.
Engel - S
S
Date: 2022.03.16 10:37:14 -04'00'

Robyn M. Engel, DVM
Animal Welfare Program Specialist
Office of Laboratory Animal Welfare

cc: IACUC Contact



March 1, 2022

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

Programmatic Issue: Inventory Management

Funding Agency: N/A

Dear Dr. Morse:

In accordance with PHS Policy IVF.3b, the University of Kansas Medical Center (KUMC) Institutional Animal Care and Use Committee (IACUC) is reporting a programmatic deviation from the provisions of the *Guide* and our institutional policies and SOPs.

During the months of November and December 2021, Laboratory Animal Resources (LAR) contacted the office of Regulatory Affairs for Biological Sciences (RABS) to report multiple inventory management issues, including inventory tracking, stock rotation, and product storage deficiencies leading to the unintentional provision of expired feed, shortages of disposable water bottles and shortages of other animal supplies. The pandemic has created additional pressures for the LAR to manage supplies due to the continued shortages and increased costs.

Corrective Actions:

These issues were first discussed at the regularly convened IACUC on 12/21/21. Potential underlying factors were identified. For example, a mismatch between specific manufacturer recommendations and general LAR SOPs led to an unnecessarily premature expiration of primate chow. In another example, a misunderstanding of lot-specific expiration and storage recommendations led to the unintentional provision of expired specialty rodent feed. In addition, informal inventory tracking and ordering, uncontrolled access, and a lack of effective lines of communication and feedback contributed to the issues identified. After discussion, the IACUC

Brent Morse, DVM, DACLAM
March 1, 2022
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required LAR management to develop concrete solutions with assistance from RABS and report back at upcoming meetings.

The LAR implemented several changes to improve inventory management. SOPs have been updated to be consistent with manufacturer information to provide more flexibility and direction regarding expiration dates and proper storage of feed, bedding and disposable water bottles. New inventory management software has been implemented that includes threshold algorithms and alerts to facilitate ordering and prevent shortages. Where possible, given space limitations, working inventory has been relocated apart from supply reserves to control access and help ensure stock rotation. In addition, to assist the facility manager, a dedicated husbandry staff member has been trained to track inventory on a weekly basis and additional staff has been empowered to provide general feedback regarding inventory levels and expiration. The QA/QC will track and report summary inventory management information monthly to the IACUC. Importantly, LAR management has demonstrated to RABS how these changes will better assure that supplies will be maintained in a manner consistent with the facility's Emergency Plan.

These solutions were presented to the regularly convened IACUC on 1/18/22 and again on 2/15/22 with further clarifications. The IACUC determined that satisfactory progress had been made and after discussion on 2/15/22 determined that the issues had been properly identified and resolved and voted unanimously to report the incident as a programmatic issue. This information is also being provided to the Association for the Accreditation of Laboratory Animal Care (AAALAC).

The IACUC, RABS and LAR will continue to work together to identify and resolve programmatic concerns to fulfill their responsibility for continuing review of KUMC's animal program.

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: 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, March 4, 2022 7:09 AM
To: Nathan Culley
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Report for the University of Kansas Medical Center A3237-01

Thank you for these reports, Dr. Culley. They appear to be complete. We will send a response soon.

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

From: Nathan Culley <nculley@kumc.edu>
Sent: Thursday, March 3, 2022 5:18 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: [EXTERNAL] Report for the University of Kansas Medical Center A3237-01

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and are confident the content is safe.

Dr. Morse,

Please find attached, two (2) animal welfare compliance report letters from the University of Kansas Medical Center (A3237-01). No preliminary reports were sent for these two. Please let me know if you have any further questions regarding the report. 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)