



DEPARTMENT OF HEALTH & HUMAN SERVICES

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NATIONAL INSTITUTES OF HEALTH

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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

January 4, 2022

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

Ms. Steffani Webb
Vice Chancellor for Administration
Institutional Official
University of Kansas Medical Center
3901 Rainbow Road, (b) (4)
Kansas City, KS 66160

Dear Ms. Webb,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your December 6, 2021 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. Your letter supplements the preliminary email report to this office on November 16, 2021. According to the information provided, OLAW understands that on November 5, 2021 the Principal Investigator (PI) reported an incidence of protocol drift to the Office of Regulatory Affairs for Biological Sciences (RABS). Specifically, two cohorts, of 48 rat each, underwent cognitive behavioral testing (Barnes and Y- Maze testing) without IACUC approval. The associated activity is PHS-funded.

Corrective and preventive measures: the RABS Post-Approval Monitor (PAM) advised research staff not to initiate any further testing until an appropriate addendum had been reviewed and approved by the IACUC. In addition, PAM confirmed that no adverse events occurred for any of the animals during the behavioral testing. An addendum describing Barnes Maze and Y-Maze cognitive behavioral testing for rats was submitted and approved by the IACUC. The IACUC determined that the corrective action was appropriate. The IACUC and RABS office, in conjunction with LAR, will continue to stress the importance of preventing protocol drift and following approved protocols to the research community during animal user training, post-approval monitoring and additional outreach efforts such as elevator signage and quarterly newsletters or institutional "town-hall" events. The RABS office has also initiated "virtual" office hours to assist the research community during this prolonged pandemic.

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. Please be sure that any associated grants are not charged for the unapproved activities. We appreciate being informed of this incident and find no cause for further action by this office.

Page 2 – Ms. Webb
January 4, 2022
OLAW Case A3237-3Q

Sincerely,

Brent C. Morse

-S

Brent C. Morse, DVM

Director

Division of Compliance Oversight

Office of Laboratory Animal Welfare

Digitally signed by Brent C.
Morse -S

Date: 2022.01.04 13:38:53
-05'00'

cc: IACUC Contact



December 6, 2021

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: Aerobic Capacity and Metabolism
IACUC Number: 2021-2614

Funding Agency: NIH-NIDDK R01DK121497

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 above Animal Care and Use Proposal (ACUP, aka protocol).

On Friday, 11/5/2021, the Principal Investigator (PI) of the above protocol reported an incidence of protocol drift to the Office of Regulatory Affairs for Biological Sciences (RABS). Specifically, two cohorts of 48 rats each underwent cognitive behavioral testing (Barnes and Y-Maze testing) without IACUC approval on ACUP listed above.

Specific Corrective Action:

The RABS Post-Approval Monitor (PAM) confirmed that the cognitive testing procedures were not approved on ACUP 2021-2614 and advised research staff not to initiate any further testing until an appropriate addendum had been reviewed and approved by the IACUC. PAM further confirmed that rats from cohort 1 underwent testing from 8/9/21 – 8/20/21 and again from 10/11/21 – 10/22/21, and rats from cohort 2 underwent testing from 10/25/21 – 11/5/21. In addition, PAM confirmed that no adverse events occurred for any of the animals during the

Brent Morse, DVM, DACLAM
December 6, 2021
Page Two

behavioral testing. An addendum describing Barnes Maze and Y-Maze cognitive behavioral testing for rats was submitted on 11/15/2021 and approved by the IACUC on 11/18/2021.

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

This report was presented at the regularly convened IACUC meeting on Tuesday, 11/16/2021. After discussion, the IACUC determined that the corrective action was appropriate and voted unanimously to report this incident. 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 preventing protocol drift and following approved protocols to the research community during animal user training, post-approval monitoring and additional outreach efforts such as elevator signage and quarterly newsletters or institutional "town-hall" events. The RABS office has also initiated "virtual" office hours to assist the research community during this prolonged pandemic. 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, December 10, 2021 7:37 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 this report, Dr. Culley. We will send a response soon.
Axel Wolff

From: Nathan Culley <nculley@kumc.edu>
Sent: Tuesday, December 7, 2021 9:20 AM
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, one (1) animal welfare compliance report letter from the University of Kansas Medical Center (A3237-01). A preliminary report was emailed on 11/16/2021. 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)

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, November 17, 2021 8:03 AM
To: Nathan Culley
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Preliminary Reports for the University of Kansas Medical Center A3237-01

Thank you for these 4 preliminary reports, Dr. Culley. We will open 4 separate case files therefore please send in separate final reports. For the programmatic issues such as 3 and 4, it may be better to wait a little longer before submitting the final to allow monitoring of the situation following implementation of the corrective actions to ensure successful outcomes.

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

From: Nathan Culley <nculley@kumc.edu>
Sent: Tuesday, November 16, 2021 5:10 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: Preliminary Reports for the University of Kansas Medical Center A3237-01

Division of Compliance Oversight,
 Below are 4 preliminary reports for the University of Kansas Medical Center (A3237-01). Contact information for each is my contact information listed below. If you would like the preliminary reports in a different format, just let me know.

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

nculley@kumc.edu

(b) (6)

Case 1:

Funding component-NIH-NIDDK R01DK121497

Description: The Principal Investigator self-reported protocol drift on 11/5/2021. Behavior testing occurred on 96 rats from August through November 2021. Personnel from the KUMC Behavior Core were also not listed on the protocol per KUMC policy. No adverse events were noted by PAM during the initial investigation.

Corrective Action: No additional behavior testing has occurred. The Principal Investigator has submitted an addendum adding the behavior testing as well as the additional personnel. Approval date will be added in the final report.

Final Report Time Frame: Report should be finalized before Dec 31st, 2021.

Case 2:

Funding component-Programmatic issue, no specific funding source.

Description: The Regulatory Affairs office for Biological Sciences (RABS) was contacted on 10/29/2021 to investigate an issue related to feed expiration for the zebrafish colony. Initial investigation noted a lack of clarity on the packaging (date of expiration vs open by date vs best used by date) and minimal supporting information from the manufacture on proper storage and usage. Due to the lack of clarity, the possibility that expired feed was given to the colony from June to October 2021 is being investigated. Preliminary veterinary reports indicate that no adverse colony effects have been noted during that time period and the Principal Investigator has noted no issues as well.

Corrective Action: The husbandry SOP on zebrafish colony management will be revised with the newest information related to the "open by" date as well as the 60 day expiration date once opened (per manufacture update). Husbandry technicians who manage the colony will be trained on the revised SOP.

Final Report Time Frame: Report should be finalized before Dec 31st, 2021.

Case 3:

Funding component-Programmatic issue-no specific funding source

Description: The RABS office was contacted on 10/27/2021 concerning a possible report of 2 rat pups going through the walk-in autoclave. Preliminary investigation noted that the incident occurred on 5/11/2021 and it could not be confirmed if the animals were alive or deceased prior to the autoclave. No communication occurred between the Lab Animal Resources (LAR) and the IACUC or RABS office prior to the report.

Corrective Action: the LAR has adjusted their SOP to emphasize to the husbandry staff to monitor all cage changing to assure all animals are transferred. Staff will be retrained on the "figure 8" technique to assure no animals are hidden by enrichment or under the bedding. For caging that investigators turn in, the cage wash staff will have enhanced training to monitor for any animals that might be left. Caging will be opened and inspected prior to placement into the autoclave. Additional discussion on the failure of communication to the IACUC will be investigated to determine where the breakdown occurred with appropriate adjustment of procedures to assure the IACUC stays informed of these situations.

Final Report Time Frame: Report should be finalized before Dec 31st, 2021.

Case 4:

Funding component-Programmatic issue-no specific funding source

Description: The RABS office was contacted on 10/27/2021 concerning an increased trend of animals being found at the cage wash after cage changing or use. Preliminary investigation noted that an increased number of animals found at the cage wash has increased from previous years. To date, 52 mice of various ages and 5 rats pups have been found in cage wash prior to bedding disposal. During the initial investigation, the process for documenting and investigating is not consistent between the cage wash, husbandry supervisors or veterinary staff. Closure of cases was sporadic with minimal follow-up for either LAR personnel or investigator personnel if a trend was noted. All animals that were alive when found were humanely euthanized.

Corrective Action: A LAR SOP will be established with the process from when the animal is found to the closure of the investigation. Trending will be reported to the IACUC monthly to determine if additional training or remediation is needed. The LAR is adjusting SOPs to keep all caging changed by staff on carts identified with the room they come from so individuals can have additional training as needed or remediation for repeat issues. Additional actions will be addressed in the final report related to better identification for investigator caging to close the loop in those situations.

Final Report Time Frame: Report should be finalized before Dec 31st, 2021.