



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

February 1, 2022

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

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 January 19, 2022 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) following up on an initial November 16, 2021, notification by email.

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: a programmatic deviation from the provisions of the *Guide for the Care and Use of Laboratory Animals*. The final report states the Regulatory Affairs Office of Biological Sciences was notified on October 29, 2021, to investigate an issue related to feed expiration for the zebrafish colony. The investigation led to contacting the manufacturer of the feed and email communications provided details on how to properly interpret dates marked on the packaging. It is understood these details were not present on the packaging or insert of the bags of feed. In response, in late July 2021, all pelleted fish feed was moved from room temperature to refrigerated storage. Given these findings from the investigation, all pelleted feed provided to zebrafish prior to this change in procedure may be considered improperly stored and expired.

On October 21, 2021, the Laboratory Animal Resources Quality Assurance/Quality Control Coordinator identified 3 bags of zebrafish feed in the refrigerated storage with a manufacturer's "Open By Date" of 10/21, but the bag was marked by LAR staff as "Opened 4/16/21" and "Opened 9/30/21" was marked on two other bags. Therefore, feed from the first bag had been opened and improperly stored prior to July 2021 and was moved to the refrigerated storage for continued use. Additional interviews indicated confusion remained and the manufacturer's labelling had been incorrectly interpreted as an expiration date.

In response to the latest findings, the expired bag of feed was removed from refrigerated storage and disposed. Multiple parties met to review the incidents and work together to create a clear consensus regarding appropriate SOP revisions and training of staff. On January 5, 2022, this training was implemented, and the revised SOP was officially posted. It is understood no adverse colony effects occurred during the time frames of concern regarding use of expired feed. Per the report, the IACUC considered the issues properly identified and corrected and voted to report the matter as a programmatic issue.

Page 2 – Dr. Webb
February 1, 2022
OLAW Case A3237-3R

It is noted that this research project is not supported by PHS funding. 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,

Jacquelyn
T. Tubbs -S

Digitally signed by
Jacquelyn T. Tubbs -S
Date: 2022.02.01
15:26:45 -05'00'

Jacquelyn Tubbs, DVM, DACLAM
Senior Animal Welfare Program Specialist
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC Contact

January 19, 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: Zebrafish Feed Expiration

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*.

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 regarding date labelling and proper storage on product packaging and accompanying paperwork. Email communication from the manufacturer to Laboratory Animal resources on 7/27/21 indicated that dates marked on packaging are "Open By Dates" and that bags opened by this date and put in refrigerated storage may be used for 60 days before being considered expired. The information provided via the email was not present on the packaging or insert. Subsequently, in late July 2021, all pelleted fish feed was moved from room temperature to refrigerated storage. Therefore, given the ambiguous information from the vendor, all pelleted feed given to zebrafish prior to this change in procedure may be considered improperly stored and expired.

However, on 10/21/2021, the Laboratory Animal Resources Quality Assurance/Quality Control Coordinator (LAR QA/QC) observed 3 bags of zebrafish feed in refrigerated storage with a manufacturer's "Open By Date" of 10/21, one of which was marked by LAR staff as "Opened 4/16/21" and the other two marked "Opened 9/30/21". Therefore, given the information described in the previous paragraph, feed from this first bag had been opened and improperly stored prior to July 2021, was subsequently moved to refrigerated storage and continued to be

Brent Morse, DVM, DACLAM
January 19, 2022
Page Two

provided well beyond 60 days after opening, presumably at least until the other two bags were opened in September 2021. Further interviews with the LAR Husbandry and Facilities managers indicated that continued confusion remained, and that manufacturer's labelling (10/21) had been incorrectly interpreted as an expiration date.

Corrective Action:

The expired bag of fish feed was removed from refrigerated storage and disposed. LAR veterinary staff, QA/QC, facilities manager, and husbandry manager all met to review the incidents in comparison with email communications from the manufacturer and worked together to form a clear consensus regarding appropriate SOP revisions and training of pertinent staff. This training was implemented and on January 5, 2022, and revised SOP 18.03 Husbandry of Zebrafish was officially posted. Further examination of veterinary reports and PI notes indicated no adverse colony effects during the time frames of concern due to provision of expired feed.

This incident was initially presented at the regularly convened IACUC meeting on Tuesday, 11/16/21 and was revisited during the subsequent meeting on 12/21/21. The IACUC determined that the issues were 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: Wednesday, January 26, 2022 6:53 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. We will send responses soon.

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

From: Nathan Culley <nculley@kumc.edu>
Sent: Friday, January 21, 2022 10:13 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: [EXTERNAL] RE: 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 letter from the University of Kansas Medical Center (A3237-01). A preliminary report was emailed on 11/16/2021 for 3412_001. 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.