



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR U.S. 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

March 4, 2022

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

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 February 17, 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 following up on an initial November 17, 2021 notification by email.

According to the information provided, this Office understands that the University of Kansas Medical Center Animal Care and Use Committee (ACUC) determined that instances of noncompliance occurred with respect to: animals found in autoclave and cagewash facilities. The final report states on October 27, 2021, the Office of Regulatory Affairs for Biological Sciences (RABS) was notified that animals were discovered at the Laboratory Animal Resources (LAR) autoclave and cagewash facilities.

It is stated the RABS Post-Approval Monitor (PAM) found that on May 11, 2021, two rat pups were discovered in a cage that went through a walk-in autoclave. LAR management could not determine the responsible party or determine whether the animals were alive or dead prior to autoclave. This information had not been communicated to RABS or the IACUC prior to October 27, 2021. Per the report, LAR management has been tracking incidents of animals discovered alive or dead at cagewash facilities since 2015. Investigative results regarding the incident revealed that individual roles and responsibilities were unclear and poorly coordinated. It was also revealed that follow-through and remediation efforts were inconsistent and none of this information had been provided to the RABS or the IACUC prior to October 27, 2021.

These findings were presented to the IACUC on November 16, 2021. The committee mandated that a corrective action plan be developed and required pertinent summary data be included in the monthly QA/QC report from LAR to the IACUC. Ultimately, LAR management presented modifications to the standard operating procedure (SOP) for cagewash operations which more clearly defined roles and responsibilities and immediate actions upon finding dirty cages containing alive or dead animals. Also, additional training for the cagewash staff occurred regarding cages entering the autoclave to allow for an additional level of scrutiny. The IACUC determined these changes were necessary and appropriate, but also determined that proactive education outreach was appropriate to achieve long term improvement. Discussions also included development of a new SOP regarding the process of how dirty cages are delivered to cagewash and autoclave facilities. It is stated a motion to proceed with the outlined plan including completion of the new SOP and development of a new training module was approved.

On January 18, 2022, the IACUC reviewed and approved a new SOP and agreed a new video prepared by the LAR Training Coordinator was ready for use for training both LAR and research personnel. It is stated the IACUC was notified that recent tracking indicated a decrease in incident and appropriate follow-through and remediation per SOP. The committee considers the programmatic issue has been properly identified and resolved.

It is noted that PHS funding is not associated with this incident. 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: 2022.03.04
13:21:46 -05'00'

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

cc: IACUC Contact

February 17, 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: Rodents Found at Autoclave/Cagewash

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*.

The Office of Regulatory Affairs for Biological Sciences (RABS) was contacted on 10/27/21 to investigate incidents of animals found at Laboratory Animal Resources (LAR) autoclave and cagewash facilities.

The RABS Post-Approval Monitor (PAM) found that on 5/11/2021, two rat pups were found in a cage that had gone through a walk-in autoclave that is used to sterilize dirty cages and bedding from quarantined rat housing rooms (aka "D-status" rooms). LAR management was unable to identify the responsible party or determine whether the rats were alive or dead prior to autoclave. In addition, this information had not been communicated to RABs or the IACUC prior to 10/27/21.

Additionally, the PAM found that LAR management has been tracking incidents of animals found alive or dead at cagewash facilities since 2015. However, during further investigation, PAM determined that individual roles and responsibilities were unclear and poorly coordinated, and that follow-through and remediation efforts were inconsistent. Importantly, none of this information had been communicated to RABs or the IACUC prior to 10/27/21.

Corrective Action:

These findings were presented to the regularly convened IACUC on Tuesday, 11/16/21. During discussion, the committee expressed concern regarding the lack of communication, mandated that a clear and effective corrective plan be developed and discussed in subsequent meetings, and required

Brent Morse, DVM, DACLAM
February 17, 2022
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that pertinent summary data be included in the monthly QA/QC report from the LAR to the IACUC. Additionally, the IACUC voted unanimously to report these concerns to relevant regulatory agencies as a programmatic issue. A preliminary report was sent to Office of Laboratory Animal Welfare (OLAW) on 11/17/21 with the expectation that complete reports be sent once the issues had been satisfactorily addressed.

Discussion continued during the convened IACUC on Tuesday, 12/21/21. LAR management presented modifications made to SOP 1.02 Cagewash Operations which more clearly defined roles and responsibilities and immediate actions upon finding dirty cages containing alive or dead animals. Additional training for the cagewash staff also occurred related to caging going into the autoclave to allow for an additional level of scrutiny for prevention. In addition, discussion included development of a new SOP with proposed changes to the process for bringing dirty cages to cagewash or autoclave facilities that would aid in determination of responsible parties, as well as subsequent remediation strategies. The IACUC agreed that many of these changes were necessary and appropriate, but also determined that proactive educational outreach was the best option for achieving long term improvement. A motion to proceed with the outlined plan including completion of the new SOP and development of a new training module was approved.

During the convened IACUC on Tuesday, 1/18/22, the committee reviewed and was satisfied with the development of SOP PROG 10.02, Missing, Escaped, or Unproperly Disposed Animals. In addition, the IACUC agreed that a new video prepared by the LAR Training Coordinator was ready to be utilized for training of both LAR and research personnel. This video was sent from our IACUC Director to PIs on 1/19/21 with the requirement that they and all lab members log in separately to view the video and thus confirm that training had been completed. Finally, the IACUC was informed that recent tracking indicated a decrease in incidents and appropriate follow through and remediation per SOP. After discussion, the IACUC determined that this programmatic issue had been properly identified and resolved and ready to be reported as such. 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, February 23, 2022 8:29 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, M.S., D.V.M.
Deputy Director, OLAW

From: Nathan Culley <nculley@kumc.edu>
Sent: Monday, February 21, 2022 4:50 PM
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, one (1) animal welfare compliance report letter from the University of Kansas Medical Center (A3237-01). The two remaining items from a preliminary report emailed on 11/16/2021 were combined into this letter. The IACUC determined that the incidents were related and the programmatic changes implemented helped correct the core issues for both. 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.