



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

November 9, 2021

Re: Animal Welfare Assurance
#A3237-01 (OLAW Case 30)

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 October 28, 2021 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: the conduct of animal-related activities prior to IACUC review and approval. The final report states a Principal Investigator (PI) reported an incidence of protocol drift. Specifically, two cohorts of mice were placed on low-potassium diets without IACUC approval. The Post-Approval Monitor (PAM) confirmed that the utilization of low-potassium diets was not included on the *de novo* Animal Care and Use Proposal. PAM recommended the research staff not initiate any further low-potassium experiments until an appropriate addendum was reviewed and approved by the IACUC. It is understood that the addendum has been submitted and was approved September 24, 2021.

The IACUC reviewed the matter at a convened meeting on October 19, 2021. The committee determined the corrective action plan was appropriate and that the matter was reportable to OLAW. It is noted that this research is 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

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

Digitally signed by Jacquelyn
T. Tubbs -S
Date: 2021.11.09 15:31:58
-05'00'

cc: IACUC Contact



October 28, 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: Regulation of renal claudins
IACUC Number: 2020-2584

Funding Agency: NIH-NIDDK R01DK115727

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 Monday, 9/16/21, the Principal Investigator (PI) of the above protocol reported to the Director of the Office of Regulatory Affairs for Biological Sciences (RABS) of an incidence of protocol drift. Specifically, two cohorts of mice were put on low potassium diets (4 mice from 7/30/20-8/6/21, and 5 mice from 8/10/20-8/17/21) without IACUC approval. This matter was turned over to the Post-Approval Monitor (PAM) for further investigation and resolution.

Specific Corrective Action:

The PAM confirmed that although a study was utilizing low-potassium diet was approved on the previous version of the above ACUP (via addendum 2017-2428.10 on 2/10/2020), this study was not included on the *de novo* ACUP 2020-2584 (approved 9/15/20). Additionally, while low-potassium diet studies were excluded, similar studies involving low-calcium diets were described and approved in the current protocol listed above. PAM advised research staff not to initiate any

Brent Morse, DVM, DACLAM
October 28, 2021
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further low-potassium experiments until an appropriate addendum had been reviewed and approved by the IACUC. Such an addendum was submitted on 9/22/21 and approved on 9/24/21.

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

This report was presented at the regularly convened IACUC meeting on Tuesday, 10/19/21. 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, November 5, 2021 7:35 AM
To: Nathan Culley
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Reports 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: Wednesday, November 3, 2021 10:27 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: Reports 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. 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)