



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 1, 2021

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

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 12, 2021 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 the principal investigator (PI) for a rabbit salmonella vaccine trial self-reported missing records for weights and dehydration checks, which were parameters identified in the protocol as humane endpoints. The post-approval monitor (PAM) also found through records review that a different serovar of salmonella was used that was not previously approved on the protocol. The PAM review noted that all other animal welfare measures were followed and that no rabbits progressed beyond the defined humane and experimental endpoints of the study. The rabbits involved were supported by PHS funds.

Corrective and preventive measures included a stipulation that an addendum to the protocol must occur prior to any further studies being initiated. The addendum has been approved and includes the additional serovar and revised clinical signs monitoring. The Institutional Animal Care and Use Committee (IACUC) also counseled the PI on the importance of accurate record keeping based on the approved methods in the protocol and notified the PI that continued noncompliance would result in additional remediation. The PAM has been tasked by the IACUC to review records from the next vaccine challenge to assure completeness.

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. 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  
Date: 2021.11.01 13:41:05 -04'00'

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

cc: IACUC contact

Dr. Robert M. Gibbens, USDA, APHIS, Animal Care



October 12, 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:** Vaccines to counter emerging antibiotic resistance  
**IACUC Number:** 2020-2580

**Funding Agency:** NIH-NIAID R01AI138970

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 non-compliance event because of a deviation from the above approved IACUC protocol.

On Monday, 9/13/21, a self-report from the Principal Investigator (PI) of the above protocol detailed missing records for weights and dehydration (skin tent) in a rabbit salmonella vaccine trial. Both parameters were identified in the protocol for humane endpoints. In a review of medical/experimental records it was also noted by the Post-Approval Monitor (PAM) that a different serovar of salmonella was used that was not previously approved on the protocol. The PAM review noted that all other animal welfare measures were followed and that no rabbits progressed beyond the defined humane and experimental endpoints of the study.

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

This report was presented at the regularly convened IACUC meeting on Tuesday, 9/21/21. After discussion, the IACUC voted unanimously to report this incident of noncompliance due to the use of an unapproved serovar and lack of record keeping. The IACUC further stipulated that an addendum adding the serovar and revised clinical signs monitoring, in consultation with the veterinary staff, must occur prior to any further studies being initiated.

Brent Morse, DVM, DACLAM  
October 12, 2021  
Page Two

A communication was sent to the PI on 9/28/21 from the Chair of the IACUC detailing the requirements of the addendum as well as the importance of accurate recording keeping based on the approved methods noted in the protocol. Continued non-compliance would result in additional remediation. An addendum was approved by the IACUC on 10/4/21 detailing the additional serovar and revised clinical signs monitoring. Additionally, the IACUC tasked the PAM to review records from the next vaccine challenge to assure completeness.

This information is also being provided to the AAALAC, Int.

The IACUC and RABS office, in conjunction with LAR, will continue to stress the importance of proper record keeping 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:** Wednesday, October 13, 2021 9:15 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:** Wednesday, October 13, 2021 9:13 AM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Subject:** Report for the University of Kansas Medical Center A3237-01

Dr. Morse,

Please find attached, one (1) animal welfare compliance report letter 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](mailto:nculley@kumc.edu)

(b) (6)