



DEPARTMENT OF HEALTH & HUMAN SERVICES

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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

March 16, 2022

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

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 March 1, 2022 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 12 rabbits were orally infected with Salmonella as part of a vaccine trial, but none of the rabbits developed expected clinical signs. The rabbits were euthanized as the protocol requires naïve animals and they were no longer suitable candidates. Upon review, it was discovered that the animals were not fasted prior to infection per protocol, and this omission may have contributed to the lack of clinical signs. The rabbits involved were supported by PHS funds.

Corrective and preventive measures included the addition of pre-challenge fasting to an existing pre-procedural checklist already used to facilitate coordination between research and veterinary staff. In addition, prior to performing any procedures, the completed checklist will now be sent to research staff as an additional assurance. The protocol will be reviewed by veterinary staff prior to each procedural event. Finally, the importance of preventing protocol drift and following approved protocols will be stressed during animal user training, post-approval monitoring, and other outreach efforts by the IACUC and Regulatory Affairs for Biological Sciences office.

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 -S

Digitally signed by Robyn M.
Engel -S
Date: 2022.03.16 10:33:13 -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

March 1, 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

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 a deviation from the provisions of the *Guide*.

On Tuesday, 1/4/21, a cohort of 12 rabbits was orally infected with Salmonella as part of a vaccine trial. None of the rabbits presented with expected clinical signs and at 11 days post-challenge the animals were removed from study and humanely euthanized. The above ACUP requires naïve rabbits, thus were not usable for additional trials. Upon review, it was discovered that the animals were not fasted prior to infection per protocol. This omission may have contributed to the lack of clinical signs and subsequent removal of the animals as suitable candidates for further study. The PI notified the RABS office of the issue on 1/20/22.

Corrective Action:

A pre-procedural checklist is used for this study to facilitate coordination between research and veterinary staff, but it did not include pre-challenge fasting. In the case described above, fasting was mistakenly omitted, because under normal circumstances fasting may lead to GI disturbances in rabbits. The checklist has now been revised accordingly. In addition, prior to

Brent Morse, DVM, DACLAM
March 1, 2022
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performing any procedures, the completed checklist will now be sent to research staff as an additional assurance. Finally, the protocol will be reviewed by veterinary staff prior to each procedural event.

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

This report was presented at the regularly convened IACUC meeting on Tuesday, 2/15/22. After discussion, the IACUC determined that the corrective action was appropriate and voted unanimously to report this incident of protocol drift that may have contributed to the loss of animals as suitable study subjects. 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 virtual training opportunities.

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, March 4, 2022 7:09 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. They appear to be complete. We will send a response soon.

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

From: Nathan Culley <nculley@kumc.edu>
Sent: Thursday, March 3, 2022 5:18 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: [EXTERNAL] Report for the University of Kansas Medical Center A3237-01

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Dr. Morse,

Please find attached, two (2) animal welfare compliance report letters from the University of Kansas Medical Center (A3237-01). No preliminary reports were sent for these two. 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)