



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) 402-7065

June 14, 2019

Re: Animal Welfare Assurance
#A3237-01 (OLAW Case 2X)

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 June 5, 2019 letter regarding noncompliance with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals at the University of Kansas Medical Center, which had not been preceded by a preliminary report to OLAW. According to the information provided, our office understands that three cages of young adult mice that were part of a PHS funded activity underwent tail snip biopsies for genotyping without provision of anesthesia or analgesia, which is required for adult mice as per IACUC policy. Upon review of the animal use protocol for this procedure, the approved protocol did not have complete information for this procedure.

Corrective measures consisted of counseling for the P.I. by the veterinary staff regarding tail snips. Going forward, the P.I. agreed to perform the procedure on animals under 17 days of age, in order to avoid using anesthetics and analgesics that could confound study results. As a result, no amendment of the protocol was required by the IACUC.

Corrective measures for the IACUC involved training and outreach by the Office of Research Affairs to ensure that animal use protocols are appropriately reviewed, and that the IACUC addresses instances where protocols are unclear or have insufficient information.

In addition, the Office of Research Affairs improved communications regarding the IACUC policy on genotyping.

Based on its assessment of this explanation, OLAW understands measures have been taken to prevent recurrence of this problem. OLAW concurs with the actions taken by your institution to comply with the PHS Policy on Humane Care and Use of Laboratory Animals. We appreciate having been informed of this matter and find no cause for further action by this office.

Sincerely,

(b) (6)

Nicolette Petervary, VMD, DACAW
Veterinary Medical Officer
Office of Laboratory Animal Welfare

cc: IACUC Contact

June 5, 2019

Axel Wolff, MS, DVM
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: Control of mutant p53 stability via the mevalonate pathway-DNAJA1 axis
IACUC Number: 2016-2366

Funding Agency: NIH-NCI R01-CA214916-01A1

Dear Dr. Wolff:

In accordance with PHS Policy IV.F.3, the University of Kansas Medical Center (KUMC) Institutional Animal Care and Use Committee (IACUC) is reporting a deviation from the provisions of the Guide and our institutional policies and SOPs.

On Monday, April 29, 2019, the office Research Affairs for Biological Sciences (RABS) received a report from Laboratory Animal Resources (LAR) that three cages of adult mice, ages ranging from 42-49 days, underwent tail snip biopsies for genotyping without provision of anesthesia or analgesia as required by IACUC policy. Additionally, upon review of ACUP 2016-2366, the PAM determined that required information regarding tail biopsy procedures was mistakenly left incomplete and that this omission was not corrected during review.

Specific Corrective Action:

LAR veterinary staff counseled the PI regarding provision of analgesia for mice aged 17-20 days and anesthesia in addition to analgesia for mice exceeding 21 days due to tail vertebral ossification as pups mature. Veterinary staff further recommended that the PI submit an addendum to allow tail biopsies between days 17-20 with the provision of meloxicam for analgesia. However, due to concerns regarding confounding effects of NSAID administration on

Axel Wolff, MS, DVM
June 5, 2019
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tumor progression, the PI assured veterinary staff that tail biopsies would no longer be taken past 16 days of age, thus an addendum would be unnecessary.

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

This information was presented to the convened IACUC on May 21, 2019. After discussion, the committee determined that remediation efforts between LAR veterinary staff and research staff were appropriate and, based upon OLAW Guidance notice NOT-OD-05-031, voted unanimously to report the incident.

Importantly, RABS will continue to stress the importance of performing diligent and thorough review of animal care and use proposals in its educational and training outreach efforts to the IACUC. Particular emphasis will be given to the need to capture required details in the appropriate sections of our ACUP forms. A review of training and communications related to the IACUC policy on genotyping was completed noting that the information was provided to the research community in a timely manner. Additional communication methods (elevator signs, compliance newsletter, and focused email communications) will be implemented to help assure the research community is made aware of any changes that occur in the animal care and use program.

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

(b) (6)

Nathan Culley, DVM, DACLAM, Chair, IACUC
Douglas Brandt, DVM, Executive Director, Laboratory Animal Resources, Attending Veterinarian

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Tuesday, June 11, 2019 7:58 AM
To: Nathan Culley; OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Incident Report for the University of Kansas Medical Center A3237-01

Thank you for providing this report Dr. Culley. We will send an official response soon.

Best regards, Brent Morse

Brent C. Morse, DVM, DACLAM
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health

From: Nathan Culley <nculley@kumc.edu>
Sent: Monday, June 10, 2019 9:24 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: Incident Report for the University of Kansas Medical Center A3237-01

Dr. Wolff,

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 report.

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)