



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

January 6, 2020

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

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 December 18, 2019 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. 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: administration of expired acepromazine to 144 rats for liver ischemia reperfusion procedures. Semi-annual inspections discovered the drug had an expiration date of January 2018, and further investigation revealed it had been used past expiration. Laboratory animal monitoring records maintained by the PI indicated normal anesthetic recovery and no adverse events for all potentially affected animals. It is noted that this research is PHS supported.

The PI met with the Post Approval Monitor to review the deficiency and develop a plan to better track drug expiration dates and prevent recurrence in the future. Corrective actions included:

- 1) Visual reminders in drug cabinets and addition of drug expiration date reminders to shared laboratory calendar when drugs are initially procured.
- 2) Laboratory record sheets were modified, and drug lot numbers and expiration dates will be recorded as an administrative control to prevent the use of drugs in animal studies past expiration.

The above information was presented to the convened IACUC on November 19, 2019. The committee voted that the lab's response was appropriate and voted to report this incident. To address the concern that previous semiannual inspections did not identify this finding, additional IACUC training will occur prior to the next semiannual inspection related to review of expiration dates to assure better coverage of monitoring during the inspections. A review will occur at a convened meeting in addition to a new handout/checklist to assist the IACUC members during inspection.

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.

Page 2 – Ms. Webb
January 6, 2020
OLAW Case A3237-3C

Sincerely,

(b) (6)

Jacquelyn T. Tubbs, DVM
Veterinary Medical Officer
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC Contact



December 18, 2019

Brent Morse, 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: Liver steatosis and hepatic ischemia and reperfusion injury
 IACUC Number: 2019-2522

Funding Agency: NIH-NIAAA R21AA026904

Dear Dr. Morse:

In accordance with PHS Policy IV.F.3.a, the University of Kansas Medical Center (KUMC) Institutional Animal Care and Use Committee (IACUC) is reporting the following instance of noncompliance with PHS Policy due to deviation from the *Guide* and our institutional IACUC Policies.

During IACUC Semi-Annual Inspections on 10/22/19, acepromazine with an expiration of January 2018, was found and subsequently disposed of at the time of inspection. Upon further investigation, it was determined that the drug had been used past expiration on 144 rats for liver ischemia reperfusion procedures with experimental endpoints ranging from 1-24 hours post-op. Importantly, detailed laboratory animal monitoring records maintained by the PI indicated normal anesthetic recovery and no adverse events for all potentially affected animals.

Study Specific Corrective Action:

The PI met with KUMC's Post-Approval Monitor on 10/30/19 to review the deficiency and develop a plan to better track drug expiration dates and prevent recurrence in the future. Solutions to be implemented include providing additional visual reminders in drug cabinets and adding drug expiration reminders to the shared laboratory calendar when drugs are initially procured. In addition the PI has modified laboratory record sheets such that drug lot numbers and expiration dates will be recorded as an administrative control to prevent the use of drugs in animal studies past expiration.

Brent Morse, DVM
December 18, 2019
Page Two

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

This information was presented to the convened IACUC on 11/19/19. The committee voted that the lab's response was appropriate and further voted unanimously to report this incident to the relevant regulatory and accrediting agencies. In addition, the IACUC discussions included concerns that this particular incident was not identified in previous semiannual inspections. Therefore the IACUC also voted unanimously to include this incident as a significant deficiency in its report to the IO. To address this concern related to the semi-annual inspection, additional IACUC training will occur prior to the next semi-annual inspection related to review of expiration dates to assure better coverage of monitoring during the inspections. A review will occur at a convened meeting as well as a new handout/checklist to assist the IACUC members during inspection. This information is also being provided to the AAALAC, Int.

The IACUC and RABS will continue to stress the importance of maintaining and monitoring the expiration of drugs and other materials used on animals. These topics will continued to be addressed via Animal User Training, research community meetings, and/or Post-Approval Monitoring. Importantly, our training efforts for performing semi-annual inspections will include a renewed emphasis on checking for expired drugs and other materials used in live animal studies.

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 Sciences, Attending
Veterinarian

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, December 20, 2019 7:24 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 these final reports Dr. Culley. We will send official responses soon.

Best regards, Brent Morse

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

Please note that this message and any of its attachments are intended for the named recipient(s) only and may contain confidential, protected or privileged information that should not be distributed to unauthorized individuals. If you have received this message in error, please contact the sender.

From: Nathan Culley [mailto:nculley@kumc.edu]
Sent: Thursday, December 19, 2019 4:45 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: FW: Incident Report for the University of Kansas Medical Center A3237-01

Dr. Morse,

Please find attached, three (3) 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. Have a Happy Holiday!

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)