

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

July 29, 2019

Re: Animal Welfare Assurance A3063-01 [OLAW Case 1E]

Dr. Lawrence E. Cornett Vice Chancellor for Research University of Arkansas for Medical Sciences 4301 W. Markham St., MS #718 Little Rock, AR 72205

Dear Dr. Cornett,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your July 23, 2019 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of Arkansas for Medical Sciences, following up on an initial telephone report on June 27, 2019. According to the information provided, OLAW understands that two cages of mice were kept in a laboratory for ten days although this area had not been approved as a satellite facility. The weekly cage change did not occur and the mice were not monitored as required.

The corrective actions consisted of returning the cages to the vivarium, having the veterinarian check the animals and finding them in good health, counseling the Principal Investigator (PI) and technician, counseling the laboratory staff, implementing ongoing meetings with staff to discuss animal care and use, having the Institutional Animal Care and Use Committee (IACUC) approve the laboratory as a satellite facility, and having the PI and staff undergo extensive on-line and hands-on retraining.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to correct and prevent recurrence of this problem. OLAW concurs with the actions taken by the IACUC to comply with the PHS Policy.

Sincerely,

(b) (6)

Axel Wolff, M.S., D.V.M.

Deputy Director

Office of Laboratory Animal Welfare

cc: IACUC Chair

Research Administration 4301 W Markham St., #718 Little Rock, Arkansas 72205

MAIN: 501-686-5347 FAX: 501-526-7465

UAMS.edu UAMShealth.com UAMS

Lawrence Cornett, Ph.D. Associate Vice Chancellor for Research

July 23, 2019

Brent Morse, DVM Director, Division of Compliance Oversight Office of Laboratory Animal Welfare National Institutes of Health 6700B Rockledge Drive, Suite 2500, MSC 6910 Bethesda, MD 20892

Dear Dr. Morse:

The University of Arkansas for Medical Sciences (UAMS), in accordance with Assurance A3063-01 and PHS Policy IV.F.3., provides this final report of a non-compliance issue that did not result in an animal welfare issue. The event occurred under a project funded by an NIH COBRE grant, P20 GM103625.

A research technician who was transitioning out of a laboratory brought two cages of mice to the laboratory on Friday June 14, 2019, in order to complete an experiment prior to his departure. The laboratory was not listed in the IACUC-approved protocol as an approved site for the procedures performed, although it was approved for other procedures in the same protocol. Additionally, the technician forgot to return the mice to the animal facility, and they were left in the laboratory, which is not an approved satellite facility, over the weekend without proper monitoring. The technician's last day in the lab was Monday, June 17, but he still did not return the mice to the animal facility that day. The new technician also did not return the cages to the animal facility immediately, and did not properly monitor the mice or record daily observations while the mice were in the laboratory, nor did the mice receive the proper weekly cage change. The new technician returned the mice to the animal facility on Tuesday, June 25, 2019. The staff in the Division of Laboratory Animal Medicine (DLAM) noticed that the cages were returned to the facility after a ten-day absence and that the cages were dirty. They notified the Clinical Veterinarian, who checked the animals and noted no welfare issues.

The Principal Investigator was out of town at a meeting during this time and was not aware that the animals had been taken to or left in the laboratory until she was so informed by the Clinical Veterinarian. She believes that the issue resulted from a lack of communication with the laboratory staff during the change in technicians. She did not anticipate any issues during this transition as the new technician was transferring from another laboratory on campus and had experience working with animals.

The following actions were taken in order to correct this noncompliance and ensure that it does not recur:

 The IACUC compliance subcommittee (consisting of the IACUC Chairman and Vice Chairman, the Attending Veterinarian and two Clinical Veterinarians, an IACUC member, the Research Compliance Officer, the Research Compliance IACUC Analyst, the IACUC Administrator, and the Biological Safety Officer) met with the Principal Investigator and the new Research Technician on Friday, June 28, 2019, to discuss the non-compliance and how it occurred. The technician was counseled during this meeting on what the appropriate actions should have been once she discovered the cages in the laboratory.

- The Principal Investigator met with all current members of her laboratory on July 1, 2019, to discuss the non-compliance issue. She had all members review the IACUC-approved animal use protocols. They plan to continue to meet to discuss specific details on how the animal use protocols translate to caring for the animals on their projects.
- The Principal Investigator submitted an addendum to the IACUC to add her laboratory as a location for the procedures in the protocol. This addendum was approved by the IACUC addendum subcommittee on July 5, 2019.
- 4. The Principal Investigator and all members of her laboratory completed/repeated the CITI online training modules "Working with the IACUC", "Reducing Pain and Distress in Laboratory Mice and Rats", "Post Procedural Care of Rodents", "Working with Mice in Research", "Working with Genetically Modified Mice in Research", and "Biomedical Responsible Conduct of Research". They also completed/repeated several UAMS specific laboratory training modules relevant to their work including "Chemical/Laboratory Safety Refresher Training", "Blood Borne Pathogen module", "Basics of Biosafety", "NIH Guidelines for Recombinant DNA Research", and "DOT-IATA Shipping Infectious Substances".
- The Principal Investigator and all members of her laboratory received in-person training from the Clinical Veterinarian and the Research Compliance IACUC Analyst on July 15, 2019, covering appropriate animal housing and usage and other relevant IACUC policies.
- 6. The Principal Investigator on the project informed the Principal Investigator of the grant of the issue and the steps she is taking to address it.
- The noncompliance event was discussed at the IACUC full committee meeting on July 19, 2019. The committee agreed that the appropriate corrective actions have been completed and had no further recommendations.

This incident was first reported to you on June 27, 2019, via a telephone call from me as the UAMS Institutional Official.

UAMS is committed to protecting the welfare of animals used in research and appreciates the guidance and assistance provided by OLAW in this regard. Should you have any questions regarding this report, please feel free to contact me.

Thank you for your consideration of this matter.

Sincerely, (b) (6)

Lawrence E. Cornett, Ph.D.

Associate Vice Chancellor for Research and Institutional Official

Morse, Brent (NIH/OD) [E]

From:

Morse, Brent (NIH/OD) [E]

Sent:

Thursday, July 25, 2019 12:34 PM

To:

(b) (6

Cc:

Subject:

RE: Letter from Dr Larry Cornett

Thank you for providing this final report. We will send an official response 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.

----Original Message-----

From:(b) (6)

Sent: Thursday, July 25, 2019 11:43 AM

To: Morse, Brent (NIH/OD) [E] <morseb@mail.nih.gov>

Cc: (b) (6)

Subject: Letter from Dr Larry Cornett

Dr Morse,

Please see the attached letter from Dr Cornett. Let us know if you have any questions.

Thank you,

----Original Message-----

From: PADM135 [mailto:toshiba@uams.edu]

Sent: Thursday, July 25, 2019 10:24 AM

To: (b) (6)

Subject: Send data from PADM135 07/25/2019 10:23

Scanned from PADM135 Date:07/25/2019 10:23

Pages:2

Resolution:600x600 DPI

Confidentiality Notice: This e-mail message, including any attachments, is for the sole use of the intended recipient(s) and may contain confidential and privileged information. Any unauthorized review, use, disclosure or distribution is



Initial Report of Noncompliance

CLAVA	By: aw	
Date: 6/27/19	Time: PM	
Name of Person reporting: /	T	
Name of Institution: Assurance number: A 3063	Medical Services	
Did incident involve PHS funded activity?		
What happened? Mice Rept in lab one, Michagant but not lab	weetend, were interested, som not h	acted of salelad
Species involved: Mice Personnel involved: Dates and times: Animal deaths:		
Projected plan and schedule for corréction/pres	vention (if known):	8
· · ·	(17 III.O WIA).	
Projected submission to OLAW of final report from Institutional Official:		
OFFICE USE ONLY Case #	ik	