



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive - MSC 7982
Bethesda, Maryland 20892-7982
Home Page: <http://grants.nih.gov/grants/olaw/olaw.htm>

FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive
Bethesda, Maryland 20817
Telephone: (301) 496-7163
Facsimile: (301) 402-7065

May 2, 2017

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

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 April 27, 2017 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 report on April 7, 2017. According to the information provided, OLAW understands that a mouse was subjected to anesthesia, insertion of probes to measure heart and respiratory rate, and restraint in a plastic cone although none of these activities had been approved by the Institutional Animal Care and Use Committee (IACUC). The mouse survived the procedures without incident. Also one cage of mice had been housed in the laboratory over the weekend although the area had not been approved as a satellite facility.

The corrective actions consisted of informing the Principal Investigator (PI) about the issues, directing the PI to review the current protocols to ensure that all proposed activities were included and to submit amendments for any additional procedures, and informing the PI that new procedures could be tested under an IACUC approved training protocol and that alternate housing rooms were available. The institutional post-approval monitoring program will focus on laboratory training sessions for the next several months.

Based on the information provided, OLAW is satisfied that appropriate actions have been taken to investigate, correct, and prevent recurrence of the noncompliance. We appreciate having been informed about this matter and find no cause for further action by this Office.

Sincerely,

Axel Wolff, M.S., D.V.M.
Director
Division of Compliance Oversight

cc: IACUC Chair

Vice Chancellor for Research

4301 W. Markham St., #718
Little Rock, AR 72205-7199

501-686-5347
501-526-7465 (fax)

www.uams.edu



Lawrence E. Cornett, Ph.D.
lcornett@uams.edu

April 27, 2017

Axel Wolff, DVM
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
Rockledge 1, Suite 360
6705 Rockledge Drive
Bethesda, MD 20892-7982

Dear Dr. Wolff:

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 noncompliance related to an unapproved procedure performed on one mouse.

On April 4, 2017, the Attending Veterinarian and Clinical Veterinarian met with an Investigator regarding restraint alternatives for a protocol addendum he had submitted to the Institutional Animal Care and Use Committee (IACUC). During that meeting, the Investigator showed the Veterinarians data demonstrating that he had performed the proposed procedure on one mouse on March 22 without IACUC approval. Specifically, the mouse was placed in a plastic cone with subcutaneous probes inserted to measure heart and respiratory rates. The mouse was also dosed with Ketamine at two different time points during the restraint. The heart and respiration rates measured did not appear to indicate that the animal was in distress. According to the data, the animal did survive with no welfare issues. However, none of these procedures (restraint, probes, Ketamine dosing) were approved by the IACUC.

During the initial investigation to determine how the noncompliance occurred, the Attending Veterinarian received an anonymous complaint on April 10, 2017, that the Investigator had a cage of mice housed in his laboratory over the weekend. The Attending Veterinarian and the Clinical Veterinarian visited the laboratory and confirmed with the Investigator that in fact one cage of mice had been left there all weekend, even though the laboratory is not approved as a satellite facility. The Veterinarians observed the animals and did not note any concerns or welfare issues. The experiments were completed and the animals euthanized in accordance with the IACUC approved protocol that day.

This work was conducted under a center grant from the National Institute of General Medical Sciences, 5P30GM110702-03. The Principal Investigator of that grant has been informed of the situations.

In order to correct these noncompliance issues and ensure that they do not recur, the following actions were taken:

1. A meeting was held on April 12, 2017, between the Investigator, the IACUC Chairman, the Attending Veterinarian, the Clinical Veterinarian, the Research Compliance Officer, and the Research Compliance IACUC Analyst. During this meeting, discussions focused on how the noncompliance occurred, what the correct process would have been, and how to proceed in the future.
2. The Investigator has been instructed to review all current Animal Use Protocols to be certain all necessary procedures and drugs are included prior to beginning the work, even for a pilot project to determine if the procedure would work, and to submit an addendum to add procedures or drugs as necessary.
3. The Investigator was informed that he could also contact the Division of Laboratory Animal Medicine to inquire about using their IACUC-approved training protocol to test new procedures before submitting a new protocol to the IACUC.
4. The Investigator was also informed that he could contact the Division of Laboratory Animal Medicine to find an alternate housing room should he ever need to return animals at the end of the day.
5. These events were discussed at the convened IACUC meeting held on April 21, 2017.

The initial incident involving unapproved procedures was first reported to you on April 7, 2017, via a telephone call from me as the UAMS Institutional Official. As the unapproved housing was discovered during the course of our investigation into that matter, we are including it in this final report. We did not make a separate initial report of the unapproved housing incident.

In order to further educate our animal research community and hopefully reduce instances of noncompliance institution-wide, the IACUC has determined that our Post Approval Monitoring program should be enhanced for the next several months to focus more on training sessions tailored for individual labs and less on reviews of individual protocols. This process will begin immediately.

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,



Lawrence E. Cornett, Ph.D.
Vice Chancellor for Research and Institutional Official

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Thursday, April 27, 2017 4:20 PM
To: [REDACTED] OLAW Division of Compliance Oversight (NIH/OD)
Cc: [REDACTED]
Subject: RE: OLAW Letter from Larry Cornett

Thank you for sending this report. We will send an official response soon.

Sincerely, Brent Morse

Brent C. Morse, DVM, DACLAM
 Animal Welfare Program Specialist
 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: [REDACTED] [mailto:[REDACTED]@uams.edu]
Sent: Wednesday, April 26, 2017 5:23 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: [REDACTED] <[REDACTED]@uams.edu>
Subject: OLAW Letter from Larry Cornett

Attached you will find a letter from Dr. Larry Cornett at University of AR for Medical Sciences. Please let me know if you have any questions.

Thank you,

 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 prohibited. If you are not the intended recipient, please contact the sender by reply e-mail and destroy all copies of the original message.



Initial Report of Noncompliance

By: OLAWDate: 5/17/17Time: AMName of Person reporting: Council

Telephone #:

Phone Number

Fax #:

Email:

Name of Institution: U of Arkansas for Med and ScienceAssurance number: 063Did incident involve PHS funded activity? Yes

Funding component: _____

Was funding component contacted (if necessary): _____

What happened?

Mouse restrained in device for 2 hrs received ketamine.
 Neither approved. Mouse ok.

Species involved: Mouse

Personnel involved:

Dates and times:

Animal deaths:

Projected plan and schedule for correction/prevention (if known): _____

COUNSEL PE

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY

Case # _____