



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 B 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

January 31, 2018

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

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 January 22, 2018 letter reporting a non-compliance with the PHS Policy on the Humane Care and Use of Laboratory Animals at the University of Arkansas for Medical Sciences. According to the information provided it is understood that on November 14, 2017, after receiving an animal welfare concern, the Attending Veterinarian (AV) and others found 30 cages of mice stacked on top of each other in a tissue culture room not approved for overnight housing of animals. The animals, as well as clean and dirty cages and supplies, were moved to the animal facility. One mouse was found dead. It was noted that this animal activity was PHS-funded but that no grant funds had been used.

You, as the Institutional Official, requested that the PI voluntarily stop all animal work on the one protocol thought to include all animals found in the room. It was later determined that multiple protocols from the PI were involved. The PI later agreed to stop all animal work on all protocols until further notice from the IACUC. The IACUC then voted to suspend all of the PI's animal protocols and have DLAM euthanize the experimental animals since they would reach their end point prior to the suspension being lifted. Care of the breeding colony was assumed by DLAM staff.

Further corrective and preventive actions included: the completion of institution-required training by all personnel; the PI and all lab personnel must complete CITI module "Responsible Conduct of Research"; the PI and all lab personnel must meet with DLAM, Compliance and Biosafety for training, and; the IACUC Compliance Analyst will conduct a focused PAM and training visit with all lab members.

After completion of the above requirements, the IACUC voted to lift the suspensions effective January 2, 2018. The PI and research team remain on a one-year probationary period. During this period, only supervised access to research animals will be allowed until the IACUC and DLAM, Compliance, Biosafety are comfortable with the team having unsupervised access and animal use. The IACUC Compliance Analyst will monitor the activities of the lab. The Veterinarians or the IACUC Compliance Analyst will attend lab meetings on at least a monthly basis.

OLAW believes that the actions by the University of Arkansas for Medical Sciences in response to this incident were appropriate and consistent with the provisions of the PHS Policy on Humane Care and Use of Laboratory Animals. We appreciate being informed of this matter and find no cause for further action by this office.

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January 31, 2018
OLAW Case A3063-X

Sincerely,

Signature

Brent C. Morse, DVM
Acting Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC Contact

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

January 22, 2018

Brent Morse, DVM
Acting 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. 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 noncompliance related to unapproved satellite housing of 30 cages of mice which resulted in an animal welfare issue.

On Monday evening, November 13, 2017, the Attending Veterinarian received an email expressing concern that it appeared animals were being housed in a non-approved room. On Tuesday morning, November 14, the Attending Veterinarian, Clinical Veterinarian, and IACUC Compliance Analyst made an unannounced visit to the room, which is designated as a tissue culture room. The Veterinarians entered the room and discovered 30 cages of mice stacked on top of each other, with some of the cages on the floor. The cages appeared to have been there for some time. There were also over 100 both very dirty and clean cages, bedding, food, and water bottles stored in the room. The room is not an approved satellite facility, and the research team is not approved for overnight housing of their animals. The Attending Veterinarian instructed the Division of Laboratory Animal Medicine (DLAM) staff to immediately transport all cages and supplies back to the animal facility. As the DLAM staff were checking the animals and placing them into clean cages in the animal facility, one mouse was found to be dead.

In order to correct this noncompliance and ensure that it does not recur, the following actions were taken:

1. On November 14, 2017, I as the Institutional Official requested that the Principal Investigator voluntarily stop all animal work on the one protocol which we thought covered all of the animals found in the unapproved room. However, it was then learned that animals from all of her experimental protocols were found in the unapproved room.
2. The IACUC Compliance Subcommittee, which consists of the IACUC Chairman, the Attending Veterinarian, the two Clinical Veterinarians, two voting members of the IACUC, the Research Compliance Officer, the Research Compliance IACUC Analyst, and the IACUC Administrator met to discuss the noncompliance issue on November 16, 2017.

3. The IACUC Compliance Subcommittee also met with the research team, with the Principal Investigator participating via conference call, on November 16, 2017. During that meeting the IACUC Compliance Subcommittee asked the team to stop all animal work on all protocols until the full IACUC could discuss the situation at their November 17 meeting. The Principal Investigator agreed that all animal work would be stopped until further notice from the IACUC. The meeting discussions then focused on how the noncompliance occurred, what the correct process would have been, and how to proceed in the future.
4. At the November 17, 2017 convened IACUC meeting, the IACUC voted to suspend all of the Principal Investigator's animal protocols indefinitely as well as all of her staff's access to the animal facilities. It was agreed that all experimental animals should be euthanized by the DLAM staff as the animals would reach their end point prior to the suspension being lifted. It was further agreed that care of the breeding colony should be assumed by DLAM staff.
5. The IACUC Compliance Subcommittee met on November 29, 2017 to determine the criteria that must be met for the animal research privileges to be reinstated. Seven IACUC voting members in addition to the IACUC Chairman, the Attending Veterinarian, the two Clinical Veterinarians, the Research Compliance Officer, the Research Compliance IACUC Analyst, and the IACUC Administrator, participated in this meeting. From this meeting, the Subcommittee established the following initial steps to be completed before the suspension of the protocols could be lifted:
 - Personnel lacking institution-required training (lab safety, recombinant DNA, etc.) must complete the training.
 - All lab personnel including the Principal Investigator must complete the online CITI module "Responsible Conduct of Research."
 - All lab personnel including the Principal Investigator must meet with DLAM, Compliance and Biosafety for face to face training on issues pertinent to the lab and the work therein.
 - The IACUC Compliance Analyst will conduct a focused Post Approval Monitoring and Training visit with all lab members.
6. The situation was discussed again at the convened IACUC meeting held on December 15, 2017. It was reported that all of the above steps were completed by the research team. The IACUC voted to lift the suspension of the animal protocols effective January 2, 2018, but to place the Principal Investigator and the research team on a one-year probationary period. The following requirements are in place during the probationary period:
 - Initial reinstatement will require supervised access to animals until DLAM, Compliance, Biosafety, and the IACUC are comfortable with the team having unsupervised access/animal use. A Clinical Veterinarian and the IACUC Compliance Analyst will provide the supervision to all research team members during any access to and use of the research animals. During this supervised access period, the Veterinarians will assess the skill levels of all personnel and determine if additional training is necessary.
 - During the probationary period, the IACUC requires that the IACUC Compliance Analyst monitor the activities of the lab by means of regular animal room inspections and observation of procedures.
 - The IACUC also requires that the Veterinarians and/or the IACUC Compliance Analyst attend lab meetings on at least a monthly basis in order to discuss and address any questions or compliance issues that may arise during the probationary period.

The Principal Investigator and her team remain under supervised access at this time. The Clinical Veterinarian and IACUC Compliance Analyst have been working closely with the team and have attended several lab meetings as well as observed a surgery. No additional concerns have been noted to date.

The IACUC records indicate that the work in question is funded by NIH grants 7 R01 CA163838 and 5 R01 CA188500. However, review of the accounting records for both grants did not reveal any animal expenses. All expenses have been covered by the Principal Investigator's departmental start-up account.

This incident was first reported to you on November 16, 2017, 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,

Signature

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

Morse, Brent (NIH/OD) [E]

From: Morse, Brent (NIH/OD) [E]
Sent: Tuesday, January 23, 2018 10:40 AM
To: 'Cornett, Lawrence E'
Cc: Secondary Individual
Subject: RE: Letter from Dr. Larry Cornett - UAMS

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

Regards, Brent Morse

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

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From: Secondary Individual [mailto:Secondary Individual@uams.edu] **On Behalf Of** Cornett, Lawrence E
Sent: Monday, January 22, 2018 2:57 PM
To: Morse, Brent (NIH/OD) [E] <morseb@mail.nih.gov>
Cc: Secondary Individual @uams.edu
Subject: Letter from Dr. Larry Cornett - UAMS

Dr. Morse –

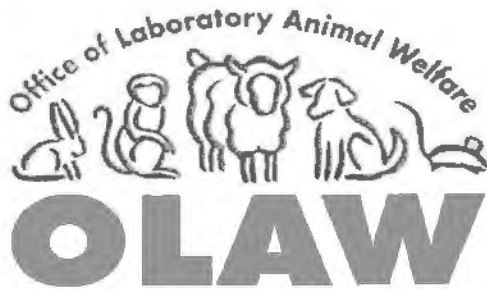
Attached you will find a letter from Dr. Larry Cornett at the University of AR for Medical Sciences. Please let me know if you have any questions.

Thank you,

Secondary Individual

University of Arkansas for Medical Sciences
 Executive Assistant, Office of the Vice Chancellor for Research
 4301 W. Markham, #718
 Little Rock, AR 72205
 Phone Number (office)
 Phone Number (fax)

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Initial Report of Noncompliance

By: *sym*

Date: 11/27/17

Time: Voicemail from

Name of Person reporting: *Larry Cornette, I.O.*Telephone #: [REDACTED]Fax #: [REDACTED]Email: [REDACTED]

Phone Number

Name of Institution: *U. Arkansas - Med Science*Assurance number: *A3063*Did incident involve PHS funded activity? ☐Funding component: ☐Was funding component contacted (if necessary): ☐

What happened? *Investigator kept ~30 cages of mice >24 hrs outside of vivarium w/o permission. One mouse dead.*

Species involved: *Mice*Personnel involved: *Investigator*Dates and times: ☐Animal deaths: *Yes*Projected plan and schedule for correction/prevention (if known): ☐Projected submission to OLAW of final report from Institutional Official: ☐

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Case # ☐