



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 U]

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 26, 2017 letters reporting two instances 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 April 3, 2017. According to the information provided, OLAW understands the following about the incidents and the corresponding corrective actions:

- 1) Three mice experienced hind limb paralysis due to tumor burden. The animals had tumor cells injected in both hind legs although the protocol was only approved for one. A post-doctoral student performed some of the injections but was not listed on the protocol and this individual and another were not listed on the Institutional Biosafety Committee (IBC) protocol.

Corrective actions: The mice were euthanized and the laboratory staff was counseled to follow the approved protocol procedures as written. The Principal Investigator was directed to review all current protocols to ensure they are complete and that all staff handling biohazards are included on the IBC protocol. One protocol was amended.

- 2) Two mice were found in poor condition after being housed several days in a laboratory not approved as a satellite facility.

Corrective actions: The student responsible was counseled on not housing animals in unapproved space, returning them promptly to the central facility, ensuring animal welfare, and following institutional animal care and transport procedures. The institutional post-approval monitoring program was enhanced to focus on training of individual laboratories.

Based on its assessment of these explanations, OLAW understands that measures have been implemented in both situations to correct and prevent recurrence of these problems. OLAW concurs with the actions taken by the institution to comply with the PHS Policy.

Page 2 – Dr. Cornett
May 2, 2017
OLAW Case A3063-U

Sincerely,

A handwritten signature in cursive script that reads "Axel Wolff, M.S., D.V.M." followed by a horizontal flourish.

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 26, 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 unapproved procedures and unapproved personnel.

On March 31, 2017, the Clinical Veterinarian noticed two cages of mice that had been injected with tumor cells, with three of those mice experiencing right hind limb paralysis subsequent to the tumor burden. The Principal Investigator was contacted and the mice euthanized. However, in reviewing the IACUC approved protocol, it was noted that injections were only approved on one flank but both flanks had been injected. Based on discussions with the Principal Investigator and the Research Associate working on the project, it was further noted that a post-doctoral student from another laboratory had performed some of the injections to train the Research Associate to perform them. That post-doctoral student was not included on the IACUC approved protocol, and neither the post-doctoral student nor the Research Associate were included on the corresponding Institutional Biosafety Committee (IBC) protocol. It was further noted that all staff involved in the procedure believed that the protocol included injections on both sides but had not actually verified such.

The work was a pilot project conducted using the Principal Investigator's departmental start-up funds.

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 3, 2017, between the Research Associate, the Attending Veterinarian, the Clinical Veterinarian, the Research Compliance Officer, and the Research Compliance IACUC Analyst to try and determine exactly what had happened and to explain the requirement to follow the protocol as written.
2. A meeting was held on April 13, 2017, between the Principal Investigator, the IACUC Chairman, the Clinical Veterinarians, 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.

3. The Principal Investigator has been instructed to review all current Animal Use Protocols to be certain all necessary procedures and personnel are included prior to beginning the work and to submit an addendum to add procedures or personnel as necessary. An addendum has been submitted to the IACUC.
4. The Principal Investigator was also advised to ensure that all personnel handling biohazards are also included on the corresponding IBC protocol.
5. These events were discussed at the convened IACUC meeting held on April 21, 2017.

This incident was first reported to you on April 3, 2017, via a telephone call from me as the UAMS Institutional Official.

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

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Thursday, April 27, 2017 8:47 AM
To: Secondary Individual
Subject: RE: Letter from Dr. Larry Cornett

Thank you. We will respond soon.

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

-----Original Message-----

From: Secondary Individual [mailto:Secondary Individual@uams.edu]
Sent: Wednesday, April 26, 2017 2:59 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Cornett, Lawrence E <CornettLawrenceE@uams.edu>; Secondary Individual @uams.edu
Subject: Letter from Dr. Larry Cornett

Attached you will find a letter from Dr. Larry Cornett. Please let me know if you have any questions.

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Vice Chancellor for Research

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

April 26, 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 housing and animal welfare concerns for two mice.

On March 31, 2017, staff in the Division of Laboratory Animal Medicine (DLAM) reported to the Attending Veterinarian that a cage of two mice had been returned to the facility in very poor condition. The census for the animal room shows that the cage was removed on March 23, 2017. The Attending Veterinarian, the DLAM Supervisor, and the Research Compliance IACUC Analyst visited the laboratory of the Principal Investigator listed on the cage card to determine what had happened. The staff in the laboratory reported that one of the post-doctoral students had called from the airport to ask that his cage of mice be returned to the animal facility as he was leaving on vacation and forgot to return them. The laboratory in which the animals were housed is not an IACUC-approved satellite housing facility. Additionally, the IACUC approved protocol does not indicate a need for housing outside the animal facility in excess of 24 hours.

The Principal Investigator was informed of the issue on Monday, April 3, 2017. He noted that the work under this protocol was conducted using financial information not federal grant funds.

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 13, 2017, between the post-doctoral student, the two Principal Investigators under whom that student works, the IACUC Chairman, the Clinical Veterinarians, 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 post-doctoral student was reminded that animals may not be kept in the laboratory overnight and that any animals not needed for the current experiments should be returned to the animal facility immediately rather than left on the bench in the laboratory where they may be forgotten.

- He was further reminded that animal care and welfare must be a top priority.
3. The post-doctoral student was also reminded of appropriate animal transport procedures as well as the notification process to DLAM staff should a cage of animals need immediate attention (cage change, water bottle refilling, etc.) upon return to the facility.
 4. These events were discussed at the convened IACUC meeting held on April 21, 2017.

This incident was first reported to you on April 3, 2017, via a telephone call from me as the UAMS Institutional Official.

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

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Thursday, April 27, 2017 8:49 AM
To: Secondary Individual
Subject: RE: OLAW Letter from Larry Cornett

Thank you.
Axel Wolff

-----Original Message-----

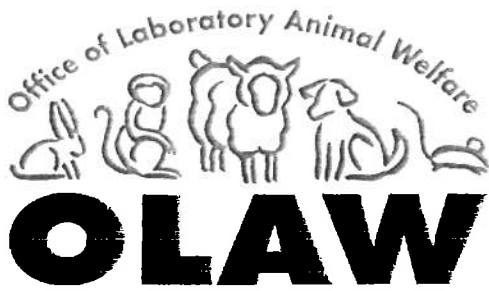
From: Secondary Individual [mailto:Secondary Individual@uams.edu]
Sent: Wednesday, April 26, 2017 5:23 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Secondary Individual@uams.edu>
Subject: OLAW Letter from Larry Cornett

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,

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Retrieved from Animal Research Laboratory Overview (ARLO)



Initial Report of Noncompliance

By: aw

Date: 4/3/17

Time:

Name of Person reporting: Larry Cornett

Telephone #:

Phone Number

Fax #:

Email:

Name of Institution: U of Arkansas for Health Sciences

Assurance number: A3063

Did incident involve PHS funded activity? NO

Funding component: _____

Was funding component contacted (if necessary): _____

What happened?

- 1) mice received tumor injections in 2 sites, only appeared for 1
Tumor burden too large; 2 PI'S not listed
- 2) 2 mice kept in lab for several days, not appeared

Species involved: Mice

Mice or

Personnel involved:

Dates and times:

Animal deaths:

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

Projected submission to OLAW of final report from Institutional Official:

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Case # _____