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

September 10, 2018

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

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 September 7, 2018 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 July 10, 2018. According to the information provided, OLAW understands that thirty three rats failed to receive the post-operative analgesia and antibiotics described in the approved protocol. The surgery involved implantation of brain tumors.

The corrective actions consisted of stopping the animal activities until the Principal Investigator and Research Associate completed online retraining. The next surgery will be monitored by the veterinarian and compliance analyst to ensure that all drugs are administered and that this is documented. The protocol was amended to switch the controlled analgesic drug to a non-controlled one.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to prevent recurrence of this problem. OLAW concurs with the actions taken by the institution 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

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

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

lcornett@uams.edu

www.uams.edu

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

UAMS
UNIVERSITY OF ARKANSAS
FOR MEDICAL SCIENCES

September 7, 2018

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 possible animal welfare issue resulting from protocol deviations. The events occurred under a project funded by internal departmental funds.

On June 28, 2018, the IACUC Compliance Analyst and Clinical Veterinarian conducted a Post Approval Monitoring (PAM) visit of a Principal Investigator who has an IACUC approved animal use protocol for orthotopic brain tumor implantation in rats. During that PAM visit, it was discovered that all of the surgeries performed (total of 33 rats) were done under general anesthesia but without administering post-operative analgesics as outlined in the IACUC approved animal use protocol. The IACUC had required the use of analgesics in order to approve the surgeries. The animals were recovered in the Principal Investigator's laboratory; therefore, the veterinarians are not aware of any specific clinical issues.

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

1. The IACUC Compliance Subcommittee, which consists of the IACUC Chairman, the Attending Veterinarian, the two Clinical Veterinarians, three 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 July 10, 2018.

2. The IACUC Compliance Subcommittee also met with the Principal Investigator and a co-Investigator on August 3, 2018, to determine how the non-compliance occurred. During this meeting, it was further discovered that the antibiotics described in the approved animal use protocol were also not administered.

3. The IACUC Compliance Subcommittee determined a corrective action plan that must be completed in order to bring the research back into compliance. Work under the protocol was voluntarily stopped by the Principal Investigator until the corrective action plan could be completed. The corrective action plan was communicated to the Principal Investigator via a letter from the IACUC Chairman on August 9, 2018, and is detailed as follows:

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a. The Principal Investigator and the Research Associate must both repeat the following CITI training modules by August 31, 2018:
    i. Reducing Pain and Distress in Laboratory Mice and Rats
    ii. Working with Rats in Research
    iii. Working with the IACUC

b. The Principal Investigator must also complete the CITI module Responsible Conduct of Research by August 31, 2018.

c. The Clinical Veterinarian and the Research Compliance IACUC Analyst will observe the next surgery performed (expected to start back in September 2018) and will follow that animal(s) all the way through the study to ensure proper administration of medications and proper monitoring of the animal(s). They will provide guidance on appropriate records for surgeries going forward so that administration of all medications is clearly documented.

4. The Principal Investigator and Research Associate did both complete the corrective action plan training requirements as of August 31, 2018.

5. Additionally, the Principal Investigator submitted an addendum to the IACUC based on the recommendation from the Clinical Veterinarian that the analgesic to be administered be changed from a controlled substance to a non-controlled substance. The addendum was approved by Veterinary Verification and Consultation on August 31, 2018.

This incident was first reported to you on July 10, 2018, 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.
Vice Chancellor for Research and Institutional Official

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Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, September 10, 2018 6:16 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Letter from Dr. Cornett

Thank you for this report. We will send a response soon.

Axel Wolff, M.S., D.V.M.
Deputy Director, OLAW

-----Original Message-----
From: (b) (6)
Sent: Friday, September 07, 2018 4:13 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: Letter from Dr. Cornett

Dr. Morse,
Please see the attached letter from Dr. Larry Cornett.

Thank you,

-----Original Message-----
From: PADM135 [mailto:toshiba@uams.edu]
Sent: Friday, September 07, 2018 3:18 PM
To: (b) (6)
Subject: Send data from PADM135 09/07/2018 15:17

Scanned from PADM135
Date:09/07/2018 15:17
Pages:2
Resolution:600x600 DPI

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A3063-2

Initial Report of Noncompliance

By: aw

Date: 7/10/18 Time: 6:00

Name of Person reporting: Larry Committ IO
Telephone #: (b) (6)
Fax #:
Email:

Name of Institution: U of Arkansas for Med Sciences
Assurance number: A3063

Did incident involve PHS funded activity? NO
Funding component: _____
Was funding component contacted (if necessary): _____

What happened?

3 rats didn't get post op analgesia. No problems noted

Species involved: Rat
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:

OFFICE USE ONLY
Case #_____

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