

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

December 18, 2017

Re: Animal Welfare Assurance #A3597-01 (OLAW Case 2N)

Dr. Fred King
Vice President for Research
West Virginia University
886 Chestnut Ridge Road,
P O Box 6216
Morgantown, WV 26506-6103

Dear Dr. King,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your December 13, 2017 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at West Virginia University. According to the information provided, OLAW understands that expired drugs were used on sixteen mice subjected to a terminal procedure. Furthermore, the euthanasia drug involved had been used as an anesthetic for the procedure.

The corrective actions consisted of labeling the expired drug, segregating the expired bottles, and amending the protocol to include Isoflurane for anesthesia. The investigator will not use expired drugs or euthanasia solution as an anesthetic. The laboratory was placed under post-approval monitoring.

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 institution to comply with the PHS Policy.

Sincerely,

Signature

Axel Wolff, M.S., D.V.M. Deputy Director Office of Laboratory Animal Welfare

cc: IACUC Chair



December 13, 2017

Brent C. Morse, DVM, DACLAM Acting Director Division of Compliance Oversight Office of Laboratory Animal Welfare Rockledge One, Suite 360 6705 Rockledge Drive - MSC 7982 Bethesda, MD 20892-7982

West Virginia University A3597-01 - New# D16-00362 NIH- 5RO1DK104791-03

Dear Dr. Morse,

I am writing to inform your office of a self-report received by one of our investigators. The investigator informed the IACUC chair that his staff accidently used expired drugs for several terminal procedures on mice. The researchers did not notice that the bottle had expired in September and subsequently, on October 25-26 performed acute procedures to harvest organs, as per the approved protocol. Sixteen mice underwent the procedure during the two days. The chair thanked the investigator for self-reporting and instructed the PI to put a label on the bottle(s) clearly indicating that the bottle(s) were expired and not to use it again.

The report was discussed at the November IACUC meeting. The committee acknowledged the report and requested that the chair send a letter to the investigator informing him not to use the expired drug and to develop a mechanism within his lab that will ensure that all drugs used on animals will not reach the expiration date. The chair will recommend that the investigator contact the animal facility for assistance on an SOP for Expiring Drugs (inventory).

After further review and discussion, it was also noted that the expired drug the investigator used was Fatal Plus, inappropriately used as an anesthetic for the acute procedures mentioned above. Dr. Wilson then contacted your office and gave a verbal report of what was discovered. He also informed your office that the non-compliance would be discussed at the next IACUC meeting. During the December meeting, the committee discussed the issue further and determined that the implementations that occurred in November by the investigator and his staff, such as, marking the bottles expired, moving the bottles to another location until disposed, and amending the protocol include Isoflurane for anesthesia, was sufficient to assure the committee of continued compliance. The PI will not be using Fatal plus as an anesthetic, nor will he use any drugs that are expired for use in animals.

The committee will continue to have close oversight of this investigator via our PAM program and if there are any further issues with this investigator, Dr. Wilson will communicate with me directly.

Please feel free to contact me or Dr. Wilson if you have any questions.

Sincerely yours,

Secondary Individual

Fred King

Institutional Official

Vice President for Research

Cc:

Dr. Matthew Wilson, WVU IACUC Chair Dr. Ida Washington, Attending Veterinarian

Secondary Individual Interim Director of ORIC Secondary Individua

RESEARCH OFFICE

PO Box 6216 | 886 Chestnut Ridge Road Morgantown, WV 26506-6216 304.293.3449 304.293.7498

Morse, Brent (NIH/OD) [E]

From:

OLAW Division of Compliance Oversight (NIH/OD)

Sent:

Thursday, December 14, 2017 11:32 AM

To:

Secondary Individual OLAW Division of Compliance Oversight (NIH/OD)

Cc:

Fred King; Matthew Wilson; Ida Washington Durkin

Subject:

RE: Report of Non-Compliance - WVU A3597-01

Thank you for this report. 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

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.

From: Secondary Individual [mailto:ondary Individ@mail.wvu.edu]

Sent: Thursday, December 14, 2017 10:12 AM

To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>

Cc: Fred King <Fred.King@mail.wvu.edu>; Matthew Wilson <Matt.Wilson@mail.wvu.edu>; Ida Washington Durkin

<ida.washingtondurkin@hsc.wvu.edu>; AAALAC International <accredit@AAALAC.org>

Subject: Report of Non-Compliance - WVU A3597-01

Dr. Morse,

Attached please see find a report of non-compliance from West Virginia University. If you have any question, please feel free to contact me.

Thank you,

Secondary Individual

Interim Director Office of Research Integrity & Compliance West Virginia University 886 Chestnut Ridge Rd. Room # Morgantown, WV 26506-6845

Phone: Phone Number