



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare
6700B Rockledge Drive, Suite 2500, MSC 6910
Bethesda, Maryland 20892-6910
Home Page: <http://grants.nih.gov/grants/olaw/olaw.htm>

FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare
6700B Rockledge Drive, Suite 2500
Bethesda, Maryland 20817
Telephone: (301) 496-7163
Facsimile: (301) 402-7065

November 18, 2019

Re: Animal Welfare Assurance
#A3124-01 (OLAW Case 10)

Dr. Wesley Byerly
Associate Vice President for Research Integrity
And Regulatory Affairs
University of Connecticut
263 Farmington Avenue, MC 1524
Storrs, CT 06030

Dear Dr. Byerly,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your November 5, 2019 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of Connecticut.


According to the information provided, OLAW understands that during IACUC semi-annual inspection in October 2019, expired ketoprofen (August 2019) was found in an animal housing room assigned to a Principal Investigator (PI). Further review of peri-operative records shows that the expired analgesic agent was used in 8 rat surgeries performed between September and October 2019. A determination was made that no animals were negatively impacted as a result of the administration of the expired agent due to the fact they were observed to be bright, alert and responsive after surgery with no signs of pain or distress.

As a corrective measure, the PI obtained in-date drug and an inventory check procedure was developed to prompt staff to reorder replacement stock once monthly prior to expiration of current supply. Additionally, retraining in provision and documentation of analgesia must be provided to personnel by facility staff.

OLAW appreciates the prompt consideration of this matter by the University of Connecticut which is consistent with the philosophy of institutional self-regulation.

We appreciate being informed of this matter and please contact us with any further questions or concerns.

Sincerely,


Nicole Lukovskiy-Akhsanov, DVM, MPH, DACLAM
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC Chair



November 5, 2019

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

RE: Animal Welfare Assurance #A3124-01

Dear Dr. Wolff:

I am writing to report an incidence of serious non-compliance that occurred at the University of Connecticut/Storrs under an approved IACUC protocol. The protocol is linked to the following NIH/NIMH award #: 1R21MH119517-01.

During the IACUC's semiannual inspection of University vivaria and labs (Oct 2019), one bottle of ketoprofen analgesia was found with an expired date (August 2019) in an animal housing room assigned to PI "LO". Further investigation and review of the pre- and post-surgical records demonstrated that the expired drug had been used in 8 rat surgeries, performed between September 1, 2019 and October 2019. It was also determined that no animals were harmed as a result of this incident, since animals were observed to be bright, alert and responsive after recovery and no signs of pain or distress were observed in these animals post-operatively.

The following corrective actions were immediately taken by the PI: (1) obtained in-date drug for use in subsequent surgeries, (2) developed an inventory check procedure to prompt staff to re-order replacement stock at least one month prior to expiration of current supplies.

This information was reviewed at the October 23, 2019 IACUC meeting, and the members determined that the non-compliance must be reported to OLAW. The IACUC also determined that, in addition to the corrective actions already taken by the PI, retraining in the provision and documentation of analgesia must be provided to listed personnel by ACS staff. These findings were communicated to the PI in a letter from the IACUC Chair.

Office of the Vice President for Research
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Retrieved from Animal Research Laboratory Overview (ARLO)

This will be our final report on this incident. Should you have any questions regarding this report, please contact me or Dr. Randall Walikonis, IACUC Chair (randall.walikonis@uconn.edu; [REDACTED] (b) (6)).

The University of Connecticut is committed to protecting the welfare of animals used in research and appreciates the guidance and assistance provided by OLAW in this regard. Thank you for your assistance in this matter.

Sincerely,
Wesley G. Byerly, Pharm.D.

[REDACTED] (b) (6)

Associate Vice President for Research Integrity and
Regulatory Affairs/Institutional Official

c: Randall Walikonis, Ph.D., Associate Professor, Department of Physiology and Neurobiology/IACUC Chair

[REDACTED] (b) (6)

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Thursday, November 14, 2019 7:27 AM
To: More, Karen
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Non-compliance Report A3124-01

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

Axel Wolff

From: More, Karen <karen.more@uconn.edu>
Sent: Wednesday, November 13, 2019 3:56 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Byerly, Wesley <wesley.byerly@uconn.edu>; Walikonis, Randall <randall.walikonis@uconn.edu>; (b) (6)
(b) (6)
Subject: Non-compliance Report A3124-01
Importance: High

Dear Dr. Wolff,
I have attached a written report from the UConn/Storrs Institutional Official (IO) documenting an incident of non-compliance that occurred at the University of Connecticut-Storrs.
If you have additional questions, please don't hesitate to contact us.
Sincerely,
Karen

Karen Moré, CPIA
RCS Interim Director
Office of the Vice President for Research
Research Compliance Services
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