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

September 3, 2019

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

Re: Animal Welfare Assurance #A3336-01 (OLAW Case 6K)

Drs. Lisa Cassis, M. Paul Murphy and Mark A. Suckow University of Kentucky
Office of the Vice President for Research
(b) (4) Main Building
Lexington, KY 40506-0032

Dear Drs. Cassis, Murphy and Suckow,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your August 26, 2019 letter regarding noncompliance with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals at the University of Kentucky, which had been preceded by a preliminary report to OLAW earlier that day. According to the information provided, our office understands that three cages of mice that were part of a PHS funded activity were not monitored according to the frequency specified in the protocol approved by the Institutional Animal Care and Use Committee (IACUC). Laboratory personnel were monitoring the animals weekly, rather than daily, and were not scoring body condition as described in the protocol. The three cages of mice were sick, found to have large tumors, and one animal required immediate euthanasia.

Corrective measures by the IACUC involved mandating that all lab members reread the protocol, and document this with a signature. In addition, lab members were retrained by the Attending Veterinarian on following protocols as written, animal monitoring and humane endpoints. The IACUC also instructed the principal investigator that in the future if he wishes to make changes to animal monitoring and humane endpoints, he must submit a protocol amendment with the supporting rationale to the IACUC for review.

Based on its assessment of this explanation, OLAW understands measures have been taken to prevent recurrence of this problem. OLAW concurs with the actions taken by your institution to comply with the PHS Policy on Humane Care and Use of Laboratory Animals. Please ensure that no charges are made to the PHS grant for any unauthorized animal activities and note that data resulting from activities that were not IACUC approved may encounter difficulties in terms of publication. We appreciate having been informed of this matter and find no cause for further action by this office at this time.

Sincerely,

(b) (6)

Nicolette Petervary, VMD, DACAW Veterinary Medical Officer Office of Laboratory Animal Welfare

cc: IACUC Contact



Office of the Vice President for Research

(b) (4)Main Building

Lexington, KY 40506-0032

www.research.uky.edu

August 26, 2019

Axel Wolff, M.S., D.V.M.
Deputy Directory
Office of Laboratory Animal Welfare
National Institutes of Health
RKL1, Suite 360, MSC 7982
6705 Rockledge Drive
Bethesda, MD 20892-7982

Reference: Animal Welfare Assurance D16-00217 (A 3336-01)
University of Kentucky

Dear Dr. Wolff:

The University of Kentucky Institutional Animal Care and Use Committee (IACUC), through the Institutional Official, is reporting the following noncompliance and deviation from the *PHS Policy on the Humane Care and Use of Laboratory Animals* as required by section IV, F, 3a of the PHS Policy.

This incident was initially reported following a semi-annual facility inspection on August 13, 2019.

Three cages of mice belonging to an investigator who uses transplanted tumor models were found to contain animals that were sick and had large tumors, including one that was immediately euthanized. The PI was contacted and euthanized the other mice within 12 hours. Subsequent review of monitoring records by the Attending Veterinarian, showed that the laboratory personnel were monitoring the tumor size weekly, rather than daily as described in the approved protocol, and that the body condition scoring system described in the approved protocol was not being applied.

The IACUC has addressed this situation by requiring all lab members working under this protocol to read the relevant protocol, and document having done so by signature. In addition, the Attending Veterinarian has emphasized with the laboratory personnel the expectation that care and use of the animals follow that as described in the approved protocol, including monitoring and application of humane endpoints. Further, the Pl was directed to submit a protocol amendment if he feels that a less stringent monitoring regimen is needed and to include

a rationale for doing so, with the IACUC potentially approving such a modification if it is determined to be reasonable.

The IACUC believes that this action is an appropriate response to prevent similar future incidents. These studies were funded through a grant from the NIH National Institute on Alcoholism and Alcohol Abuse (2R01AA017226).

If you have questions concerning this incident, please contact Dr. Mark A. Suckow, Attending Veterinarian (msuckow@uky.edu; (b) (6), Dr. M. Paul Murphy, IACUC Chair (mpmurp3@uky.edu; (b) (6)), or Dr. Lisa A. Cassis, Institutional Official (lcassis@uky.edu; (b) (6)).

Sincerely,

(b) (6)

Lisa A. Cassis, PhD Vice President for Research Committee Institutional Official

M. Paul Murphy, PhD Chair, Institutional Animal Care and Use

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Mark A. Suckow, DVM, DACLAM Attending Veterinarian

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)

Sent: Wednesday, August 28, 2019 9:43 AM

To: Suckow, Mark A.; OLAW Division of Compliance Oversight (NIH/OD)

Subject: RE: Noncompliance Reports

Thank you for providing these reports Dr. Suckow. We will send official responses soon.

Best regards, Brent Morse

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

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From: Suckow, Mark A. [mailto:msuckow@uky.edu]

Sent: Tuesday, August 27, 2019 3:59 PM

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

Subject: Noncompliance Reports

Dear Dr. Morse,

Attached please find two reports regarding noncompliance that recently occurred at the University of Kentucky. These reports follow the preliminary reports that I submitted on August 26, 2019.

Regards,

Mark A. Suckow, DVM, DACLAM
Associate Vice President for Research
Attending Veterinarian
Professor, Department of Biomedical Engineering
University of Kentucky

(b) (4) Bowman Hall
Lexington, KY 40506