



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) 480-3387

April 21, 2020

Re: Animal Welfare Assurance
#A3336-01 (OLAW Case 6R]

Dr. Lisa Cassis
Vice President for Research
University of Kentucky
(b) (4) Main Building
Lexington, KY 40506-0032

Dear Dr. Cassis,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your April 16, 2020 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of Kentucky following up on an initial April 9, 2020 notification by email.

According to the information provided, this Office understands that the University of Kentucky Animal Care and Use Committee (ACUC) determined that instances of noncompliance occurred with respect to: several cages of mice reported for concerns about post-surgical care. The final report states the mice had undergone mammary fat pad tumor resection several weeks previously. The tumors had regrown after the resection and the surgical clips had not been removed as described in the protocol. It is stated the tumors were large and some were ulcerated or cavitated. It is also reported that one mouse was lethargic and in poor body condition. The cage surgical cards listed research staff that were either not in the approved protocol or were not listed to perform the surgery. It is noted that the affected mice were promptly euthanized.

The following corrective actions were issued by the IACUC:

- No further surgeries will be performed until all remedial actions are completed.
- The PI must submit for the Attending Veterinarian's approval a plan of action establishing how recurrence of non-compliance will be prevented.
- All personnel listed on the approved IACUC protocol will complete the AALAS Learning Library modules "Common Compliance Issues" and "Post-Procedure Care of Mice and Rats in Research: Minimizing Pain and Distress."
- The PI will amend the IACUC protocol to add and/or clarify the role of research staff for the approved surgeries.

All corrective actions must be completed within 30 days. It is noted that these animals were involved in PHS funded animal activities. Based on its assessment of this explanation, OLAW understands that the University of Kentucky has implemented appropriate measures to correct and prevent recurrences of these problems and is now compliant with provisions of the PHS Policy. We appreciate being informed of these matters and find no cause for further action by this Office.

Sincerely,

(b) (6)

Jacquelyn T. Tubbs, DVM
Veterinary Medical Officer
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC Contact



Office of the Vice President for Research

311 Main Building
Lexington, KY 40506-0032
(859) 257-5294
Fax: (859) 323-2800
www.research.uky.edu

April 16, 2020

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 by email on April 9, 2020.

Several cages of mice were reported due to concerns about post-surgical care. The mice had undergone mammary fat pad tumor removal surgery several weeks previously; however, the tumors had regrown after the resection and the surgical clips had not been removed as described in the protocol. The tumors were large, and some had ulcerated or cavitated. One of the mice was lethargic and in poor body condition. The cage surgical cards listed research staff that were either not in the approved protocol or were not listed to perform the surgery. The affected mice were promptly euthanized.

In response to this noncompliance, the IACUC has issued that: 1) No further surgeries shall be performed until all remedial actions are completed; 2) The PI shall submit for the AV's approval a plan of action establishing how recurrence of non-compliance will be prevented; 3) All personnel listed on the approved IACUC protocol shall complete the AALAS Learning Library modules "Common Compliance Issues" and "Post-Procedure Care of Mice and Rats in

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Research: Minimizing Pain and Distress;" and 4) The PI shall amend the IACUC protocol to add and/or clarify the role of research staff for the approved surgeries. All four action items listed above must be completed within 30 days.

The IACUC believes that this action is an appropriate response to prevent similar future incidents. These studies were funded through grants from the NIH National Institute of Diabetes and Digestive and Kidney Diseases (1R)IDK112034-01).

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, Ph.D.
Vice President for Research
Institutional Official

(b) (6)

M. Paul Murphy, Ph.D.
Chair, Institutional Animal Care and Use Committee

(b) (6)

Mark A. Suckow, DVM, DACLAM
Attending Veterinarian

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, April 20, 2020 7:43 AM
To: Suckow, Mark A.
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Preliminary Report of Noncompliance

Thank you. We will respond soon.
Axel Wolff

From: Suckow, Mark A. <msuckow@uky.edu>
Sent: Friday, April 17, 2020 2:15 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: Re: Preliminary Report of Noncompliance

Dear Dr. Wolff,

Attached please find a final report from the University of Kentucky (Assurance #D16-00217; A3336-01) regarding a noncompliance that was reported to OLAW initially on April 9, 2020.

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
(b) (6)

From: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Sent: Friday, April 10, 2020 7:13 AM
To: Suckow, Mark A. <msuckow@uky.edu>
Cc: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: RE: Preliminary Report of Noncompliance

Thank you for this preliminary report, Dr. Suckow. We will open a new case file.
Axel Wolff

From: Suckow, Mark A. <msuckow@uky.edu>
Sent: Thursday, April 9, 2020 3:26 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: Preliminary Report of Noncompliance

Dear Dr. Wolff,

I wish to submit a preliminary report of noncompliance for the University of Kentucky (Assurance #D16-00217; A3336-01). Specifically, several cages of mice were found with tumors that had grown beyond the endpoints described in the approved protocol and with surgical staples not removed within the timeframe described in the approved protocol. Some of the mice had tumors that had abraded or ulcerated and have been subsequently euthanized. The IACUC is continuing to investigate the circumstances behind this occurrence.

Regards,

Mark A. Suckow, DVM, DACLAM
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University of Kentucky
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