



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

August 3, 2020

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

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 July 20, 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 report on July 14, 2020. According to the information provided, OLAW understands that mice undergoing castration were given a different analgesic than described in the approved protocol. No adverse outcomes were reported with the animals.

The corrective actions consisted of counseling the Principal Investigator to use only the drugs approved in the protocol or to amend the protocol prior to initiating a change.

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



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

July 20, 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 July 14, 2020.

Several cages of mice that had undergone castration surgery for experimental purposes were found to have been given an analgesic that was not included in the approved protocol. While the analgesic that had been substituted would have been acceptable, the PI had not notified the IACUC that this change had been made. There was no evidence that any mice experienced pain or distress as a result of this substitution.

In response to this noncompliance, the IACUC has advised the PI that only approved drugs listed in the protocol may be used, but that other drugs can be added by amendment, if so desired.

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 Cancer Institute R01CA192894.

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

Sincerely,

[REDACTED] (b) (6)

Lisa A. Cassis, Ph.D.
Vice President for Research
Institutional Official

[REDACTED] (b) (6)

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

Mark A. Suckow, DVM, DACLAM
Attending Veterinarian

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, July 31, 2020 7:24 AM
To: Suckow, Mark A.
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Preliminary Report of Noncompliance

Thank you for this report, Dr. Suckow. We will send a response soon.
Axel Wolff

From: Suckow, Mark A. <msuckow@uky.edu>
Sent: Tuesday, July 28, 2020 10:27 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: Re: Preliminary Report of Noncompliance

Dear Dr. Wolff,

Attached please find the final report that follows from my preliminary report of noncompliance that was submitted on 7/14/20.

Regards,

Mark A. Suckow, DVM, DACLAM

Associate Vice President for Research

Attending Veterinarian

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: Wednesday, July 15, 2020 7:22 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

CAUTION: External Sender

Thank you for this preliminary report, Dr. Suckow. We will start a new case file and look forward to receiving the final report from the IO after the IACUC has completed its investigation.

Axel Wolff

From: Suckow, Mark A. <msuckow@uky.edu>

Sent: Tuesday, July 14, 2020 10:01 AM

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, an investigator used in mice a post-operative analgesic that was not included in the approved protocol. The IACUC is investigating this matter to determine an appropriate course of action.

Regards,

Mark A. Suckow, DVM, DACLAM
Associate Vice President for Research
Attending Veterinarian
University of Kentucky
(b) (4) Bowman Hall
Lexington, KY 40506
(b) (6)

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, July 15, 2020 7:22 AM
To: Suckow, Mark A.
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Preliminary Report of Noncompliance

Thank you for this preliminary report, Dr. Suckow. We will start a new case file and look forward to receiving the final report from the IO after the IACUC has completed its investigation.

Axel Wolff

From: Suckow, Mark A. <msuckow@uky.edu>
Sent: Tuesday, July 14, 2020 10:01 AM
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, an investigator used in mice a post-operative analgesic that was not included in the approved protocol. The IACUC is investigating this matter to determine an appropriate course of action.

Regards,

Mark A. Suckow, DVM, DACLAM
Associate Vice President for Research
Attending Veterinarian
University of Kentucky
(b) (4) Bowman Hall
Lexington, KY 40506

(b) (6)