



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

March 28, 2019

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

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 March 25, 2019 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 March 15, 2019. According to the information provided, OLAW understands that mice were used in a melanoma study that was not included in the approved protocol and experimental compounds had been given by a route not listed in the protocol. One mouse died and several were weak.

The corrective actions consisted of the Institutional Animal Care and Use Committee (IACUC) directing the investigator to stop using additional animals until the protocol was amended and approved. The investigator and staff were counseled and retrained on only performing IACUC approved procedures.

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 IACUC to comply with the PHS Policy. Please also report this incident to the funding component to reconcile financial aspects regarding reimbursing the grant (R01CA192894) for unapproved animal activities. Also, inform the investigator that most journals will not accept submissions of data acquired under conditions which are noncompliant with federal policies. Once the protocol is amended, appropriate monitoring and humane endpoints need to be in place to address any morbidity/mortality on this study. Thank you for keeping OLAW apprised on this matter.

Sincerely,

(b) (6)

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

cc: IACUC Chair  
Director, Division of Laboratory Animal Resources  
Crystal Wolfrey, NCI Chief GMO



**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](http://www.research.uky.edu)

March 25, 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 by email on March 15, 2019.

An investigator who is approved to conduct studies involving rodent cancer models was determined to have used a model for a cancer (melanoma) that was not included in the approved protocol. On March 1, 2019, a Division of Laboratory Animal Resources (DLAR) employee noted several mice to be weak and one dead. Further, the investigator used an experimental compound that is included in the relevant approved protocol but via a route that is not described in the protocol.

In response to this noncompliance, the IACUC has required that the protocol be modified to accurately reflect the procedures to be conducted on animals and that no additional animals be used until the modification has been approved by the IACUC. Further, the investigator and all members of the laboratory who are listed on the protocol are required to undergo training and counseling by the Attending Veterinarian or his delegate within the next 30 days. This training will focus on the expectation that all activities involving vertebrate animals must be approved by the IACUC prior to initiation.

*An Equal Opportunity Employer*

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 Cancer Institute (R01CA192894).

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

Sincerely,

(b) (6)

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

(b) (6)

Francisco Andrade, Ph.D.  
Vice Chair, Institutional Animal Care and Use Committee

(b) (6)

Mark A. Suckow, DVM, DACLAM  
Attending Veterinarian

**Morse, Brent (NIH/OD) [E]**

---

**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Thursday, March 28, 2019 9:17 AM  
**To:** Suckow, Mark; OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: Noncompliance Report

Thank you for providing this final report Dr. Suckow. We will send an official response soon.

Best regards, Brent Morse

Brent C. Morse, DVM, DACLAM  
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:** Suckow, Mark [mailto:msuckow@uky.edu]  
**Sent:** Wednesday, March 27, 2019 1:50 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Subject:** Noncompliance Report

Attached please find a noncompliance report from the University of Kentucky.

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)

**Wolff, Axel (NIH/OD) [E]**

---

**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Friday, March 15, 2019 9:18 AM  
**To:** Suckow, Mark  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: Preliminary Noncompliance Report

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

Axel Wolff, M.S., D.V.M.  
Deputy Director, OLAW

---

**From:** Suckow, Mark <msuckow@uky.edu>  
**Sent:** Friday, March 15, 2019 9:01 AM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Subject:** Preliminary Noncompliance Report

Please note that I am submitting a preliminary noncompliance report as follows:

An investigator at the University of Kentucky (Assurance No. A3336-01) who is approved to conduct studies involving rodent cancer models was determined to have used a model for a cancer (melanoma) that was not included in the approved protocol. Several mice were found on March 1 to be weak, and one mouse was found dead. The IACUC is reviewing the incident; and the investigator has been instructed to cease this activity until it is approved by the IACUC. The activity is funded by sources that include the National Cancer Institute, as well as departmental funds. It is anticipated that the activity which is the subject of this noncompliance will be reviewed as a modification to the approved protocol in late March or April, 2019 and, if appropriate, approved. Further, the investigator and his staff will be re-instructed that all animal research activities must have received IACUC approval prior to commencement.

A summary with actions taken will be forwarded to OLAW from the Institutional Official within the several weeks.

Regards,

Mark A. Suckow, DVM, DACLAM

Attending Veterinarian

(b) (6)