



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive - MSC 7982
Bethesda, Maryland 20892-7982
Home Page: <http://grants.nih.gov/grants/olaw/olaw.htm>

FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive
Bethesda, Maryland 20817
Telephone: (301) 496-7163
Facsimile: (301) 402-7065

May 24, 2018

Re: Animal Welfare Assurance
A3261-01 [OLAW Case 2E]

Dr. Janet Weisenberger
Senior Associate Vice President for Research
The Ohio State University
(b) (4) Bricker Hall
1190 North Oval Mall
Columbia, OH 443210

Dear Dr. Weisenberger,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your May 21, 2018 letter reporting a series of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at The Ohio State University, following up on an initial telephone notification on October 25, 2017. According to the information provided, OLAW understands that a new post-doctoral fellow failed to monitor animals, provide palliative care and promptly remove animals that had attained their humane endpoints in accordance with the approved protocol. A total of fourteen mice died and an additional three moribund mice were euthanized over a period of four days as a result of the noncompliance. The IACUC suspended the protocol based on the aforementioned incidents and the previously identified violations involving laboratory personnel overseen by the same Principal Investigator (PI). Although the incidents were not PHS funded, other activities of the protocol are partially funded by National Cancer Institute (NCI) grants RO1CA185301, R35CA210087 and PO1CA095426.

The corrective actions consisted of the IACUC reviewing and approving a comprehensive management plan submitted by the PI which detailed measures to prevent recurrence and included the appointment of a mentor. Laboratory personnel were required to undergo additional training and attend multiple meetings with a Quality Improvement Specialist (QSI) over a six month period. The IACUC has since PI lifted the suspension upon review of a status update report submitted by the PI, QSI and training staff regarding training and the implementation of the management plan.

OLAW recommends that the PHS funding components be notified directly to determine the allowability of charges against the grant during the period of noncompliance for the suspended animal activities. Based on the information provided, OLAW is satisfied that appropriate actions have been taken to investigate, correct and prevent recurrence of the noncompliance. We appreciate being informed of these matters and find no cause for further action by this Office.

Sincerely,

(b) (6)

Neera V. Gopee, DVM, PhD, DACLAM, DABT
Animal Welfare Program Specialist
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC Chair

Young Kim (kimyoung@mail.nih.gov), PO, NCI

Alice Wong (chia@mail.nih.gov), Grants Management Specialist, NCI

Martinson Owusu (owusumo@mail.nih.gov), Grants Management Specialist, NCI



May 21, 2018

Janet M. Weisenberger
Senior Associate
Vice President for Research
614-247-4764 Phone

Brent Morse, DVM
Acting Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare National Institutes of Health
Rockledge One, Suite 360, MSC 7982
6705 Rockledge Drive
Bethesda, Maryland, 20817

RE: Animal Welfare Assurance #A3261-01, D16-00168

Dear Dr. Morse:

This letter reports the follow-up to an incident of noncompliance with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals at The Ohio State University. The incident involved failure to provide appropriate oversight of mice following tumor injections, which resulted in the death of animals. The Institutional Animal Care and Use Committee (IACUC) reviewed this issue at its convened monthly meetings in October and November and status of follow-up action in December 2017 and May 2018. A preliminary report was provided to OLAW on October 25, 2017 via phone.

The concerns included lack of monitoring animals, providing supportive care and timely removal of mice meeting early removal criteria, as described in the protocol. Activities involved a new post doc in the investigator's lab. Over four days, 14 mice were found dead and an additional three mice were found moribund and were euthanized. There have been several other incidents over several years involving different lab members managed by this investigator. Due to the serious and continuing nature, the IACUC voted to suspend the protocol.

The PI submitted a detailed management plan regarding steps he will take to help ensure this will not happen again including the identification of a mentor for the PI. The IACUC reviewed and approved this plan at their November meeting and lifted the suspension. Over the next six months, lab members underwent additional training and met with a Quality Improvement Specialist (QIS) on multiple occasions. The PI provided a status update regarding implementation of the management plan to the IACUC for review at their May 18, 2018 convened meeting. At that meeting, the IACUC accepted the report from the PI, QIS and ULAR training staff. At this point, training is being completed for one new employee. Although formal monitoring of his laboratory is now completed, informal periodic monitoring will continue.

The work in this incident is not funded by external agencies, but other activities of the protocol are partially funded by the National Cancer Institute (R01CA185301, R35CA210087 and P01CA095426).

The Ohio State University remains committed to ensuring the proper care and treatment of animals used in research and teaching at the institution. Funding agencies will be notified as needed. Please contact me at (b) (6) or weisenberger.21@osu.edu if you require any further information.

Sincerely,

(b) (6)

Janet M. Weisenberger, PhD
Senior Associate Vice President for Research

cc: Valerie Bergdall, OSU Attending Veterinarian
Peter Reiser, OSU IACUC Chair
(b) (6)
AAALAC International

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Tuesday, May 22, 2018 8:22 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: noncompliance report from Ohio State D16-00168

Thank you for this report, (b) (6). We will send a response soon.
Axel Wolff

From: (b) (6)
Sent: Tuesday, May 22, 2018 7:18 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: noncompliance report from Ohio State D16-00168

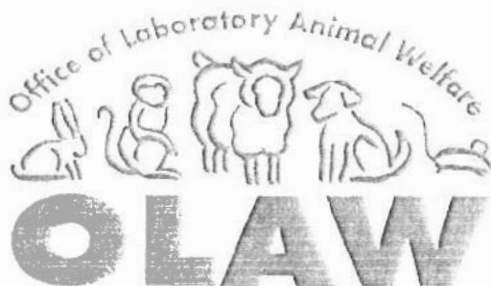
Attached is a final report from our Institutional Official at The Ohio State University regarding a non-compliance issue initially reported in October 2017. Please let me know if there are any questions.

(b) (6)



THE OHIO STATE UNIVERSITY

(b) (6)



Initial Report of Noncompliance

By: *aw*Date: *10/25/17*Time: *PM*Name of Person reporting: *(b)(6)*

Telephone #:

Fax #:

Email:

Name of Institution: *Ohio State U*Assurance number: *A3261*

Did incident involve PHS funded activity? _____

Funding component: _____

Was funding component contacted (if necessary): _____

What happened?

*Animals not monitored, 1 died, 3 euthanized*Species involved: *?*

Personnel involved:

Dates and times:

Animal deaths:

Projected plan and schedule for correction/prevention (if known): _____

Supervise protocol, need management plan from PI

Projected submission to OLAW of final report from Institutional Official:

ICE USE ONLY

IC # _____



Division of Compliance Oversight

Record of Call for Case # A3261-2E

Date & Time	Message	Initials
5-17-18 11:58 am	Spoke to (b) (6) (b) (6) IACUC meets tomorrow to discuss this incident will provide either an interim or	(b) (6)
	final report depending on the IACUC's decision in a week or two	