



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

August 22, 2019

Re: Animal Welfare Assurance
#A3021-01 (OLAW Case 3P)

Ms. Jennifer Lassner
Senior Assistant Vice President for Research
The University of Iowa
Office for the Vice President for Research
2660 University Capitol Centre
Iowa City, Iowa 52242

Dear Ms. Lassner,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your letter dated August 15, 2018 concerning a report of an incident of noncompliance with the Public Health Service Policy on the Humane Care and Use of Laboratory Animals (Policy) within the animal care and use program at the University of Iowa. According to the information provided, OLAW understands that during the period of June 11-15, 2019 a veterinary technician contacted a lab member to inform them that two mice in a cage appeared to have reached humane endpoints. The lab member observed the mice and euthanized one but not the other. The lab member notified the veterinary technician that in the lab member's assessment the second animal had not reached humane endpoints. The next day the animal was found deceased. Two days later the lab was contacted about another mouse that had reached a humane endpoint. The lab member again disagreed with the assessment and did not euthanize the mouse or contact veterinary staff. The following day the mouse developed additional clinical signs indicative of humane endpoints and was euthanized. This activity was PHS funded.

Corrective and preventive actions included counseling lab members to always consult veterinary staff if there is a difference of opinion as to the assessment of an animal's health. The lab also has amended the Animal Protocol to clarify humane endpoints. The lab members and the PI are to be trained in the new endpoints and to develop clear standardized procedures. Veterinary staff and lab members will collaborate on monitoring for the model. The lab will report back to the IACUC regarding experiments conducted with the model.

The University of Iowa's prompt reporting of this incident was consistent with the philosophy of self regulation. Similarly, the timely actions taken to respond to the issue and to prevent recurrence were appropriate. We appreciate being informed of this matter and find no cause for further action by this office.

Sincerely,

(b) (6)

Brent C. Morse, DVM
Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC Contact



**Office of the Vice President
for Research**

2660 University Capitol Centre
Iowa City, Iowa 52242-5500
319-335-2119

August 15, 2019

Axel V. Wolff, MS, DVM
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare (OLAW)
National Institutes of Health
6700B Rockledge Drive
Suite 2500, MSC 6910
Bethesda, MD 20892

Dear Dr. Wolff:

This letter is to report an incident involving mice. The University of Iowa PHS Assurance Number is D16-00009 (A3021-01). The grant number affected is NS036592.

June 11-15. On each of the noted days, a veterinary technician observed a cage of mice in varying degrees of health. The technician contacted a lab member to inform them that two mice in a cage appeared to have reached humane endpoints. The lab member observed the animals and euthanized one but not the other. The lab member notified the veterinary technician that in their assessment the second animal had not reached humane endpoints. The next day that animal was found deceased.

Two days later the lab was again contacted about a mouse that was lethargic, a protocol humane endpoint. The lab member observed the mouse but did not euthanize it as, in their assessment, it did not appear to meet humane endpoints. The lab member did not notify veterinary staff regarding his/her decision. The mouse in question developed additional clinical signs the following day which met humane endpoints and was euthanized by the lab. There had been ongoing discussions between the lab and vet staff regarding differing interpretation of the approved humane endpoints. In this case the IACUC felt the humane endpoints were met as approved in the animal protocol and the animals should have been euthanized.

The lab was contacted and subsequently met with the IACUC Training and Compliance Manager (ITCM) and the Attending Vet. The lab indicated that the emails did not appear to require euthanasia but rather allowed lab discretion to assess the animals. The lab was instructed to always consult veterinary staff if there was a difference in opinion as to the assessment of an animal's health. A separate meeting was held with the PI, Director of the IACUC Office, and clinical veterinarian regarding their humane endpoints. The lab has amended their Animal Protocol to clarify humane endpoints.

July 10, 2019: The IACUC members discussed the incident at a convened meeting. The members felt the endpoints, as currently stated in the protocol, were too stringent for the given model; however, the animals involved in the incident had indeed met the approved endpoints and the lab member incorrectly applied these to the mice involved. The IACUC members voted to report to the appropriate agencies. Included in the vote were the following requirements:

- Once the amendment with refined endpoints is approved, the PI and lab members are to meet with the ITCM to ensure all members of the lab are trained on the new endpoints and to develop clear standardized procedures for all members to follow.
- Collaborative monitoring between the lab members and veterinary staff will be established for the model (joint assessments of animals to understand whether vet and lab staff assessment agree regarding humane endpoints).
- The lab will report back to the IACUC regarding experiments conducted with the model.

I have reviewed the events and believe they were appropriately managed and fully addressed.

If you have any questions pertaining to this report, please contact me.

Sincerely,

(b) (6)

Jennifer Lassner
Institutional Official
Senior Assistant Vice President for Research

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, August 19, 2019 3:16 PM
To: (b) (6) OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Report of non-compliance incident

Thank you for providing this report. 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: (b) (6)
Sent: Monday, August 19, 2019 2:09 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: accredit@aaalac.org
Subject: Report of non-compliance incident

Good afternoon,

Please see attached reports of non-compliance at the University of Iowa.

Thank you,

(b) (6)

(b) (6)