

#### 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

January 7, 2020

Re: Animal Welfare Assurance #A3021-01 (OLAW Case 3Q]

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 December 19, 2019 letter responding to OLAW's December 12, 2019 request for additional information regarding an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at The University of Iowa.

According to the information provided, OLAW understands that 12 mice were affected by the non-compliance with nine of the mice euthanized as required by veterinary staff due to ill health and the remaining three mice euthanized due to study integrity concerns by the principal investigator.

OLAW appreciates the prompt consideration of this matter by The University of Iowa, which is consistent with the philosophy of institutional self-regulation. Based on the information provided, OLAW is satisfied that appropriate steps have been taken to investigate this incident. We appreciate being informed of this matter and please contact us with any further questions or concerns.

Sincerely (b) (6)

Nicole Lukovsky-Akhsanov, DVM, MPH, DACLAM Division of Compliance Oversight Office of Laboratory Animal Welfare

cc: IACUC contact



# Office of the Vice President for Research

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

December 19, 2019

Nicole Lukovsky-Akhsanov, DVM, MPH, DACLAM 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. Lukovsky-Akhsanov,

Thank you for your careful review of the report, #A3021-01 OLAW Case 3Q.

Regarding your questions, please find below responses to each item.

- 1) How many animals were affected?
- Twelve mice
- 2) Were the animals euthanized as part of the study or due to welfare concerns?
- Nine mice were euthanized as required by the veterinary staff due to ill health. The PI elected to euthanize the remaining three mice due to study integrity concerns.

Please let me know if you have any further questions pertaining to this report, please contact me.

Sincerely,

(b) (6)

Jennifer Lassner Institutional Official Senior Assistant Vice President for Research



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December 12, 2019

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

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 November 22, 2019 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at The University of Iowa.

According to the information provided, OLAW understands that on October 16,2019, an animal care technician observed several mice to have post-surgical complications. Upon investigation, the individual that performed the surgery was found to have completed some but not all of the required training. Additionally, the surgical closure was not performed as described in the protocol. Some of the animals had not been transferred to the correct protocol prior to surgery conducted and all the mice were euthanized.

As a corrective measure, on October 21, 2019, the Attending Veterinarian, IACUC chair and Director of the IACUC office met with the principal investigator (PI) and lab manger to discuss the concern. On November 12, 2019, the IACUC Training and Compliance Manger met with the lab member to provide retraining. Additionally, before the lab member will be allowed to perform surgery, a step-wise training process will be instated and observed for competency by the ITCM and/or veterinary staff

OLAW appreciates the prompt consideration of this matter by The University of Iowa which is consistent with the philosophy of institutional self-regulation. Based on the information provided, OLAW has the following questions:

- Where the animals euthanized as part of the study or due to welfare concerns?
- How many animals were affected?

We appreciate being informed of this matter and please contact us with any further questions or concerns.

Sincerely

Nicole Lukovsky-Akhsanov, DVM, MPH, DACLAM Division of Compliance Oversight Office of Laboratory Animal Welfare

cc: IACUC contact



November 22, 2019

# Office of the Vice President for Research

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

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 numbers affected are DK116624 and NS096246.

October 16, 2019: An animal care technician reported several mice observed to have post surgical complications. Upon investigation, a lab member was found to have performed surgery after completing some but not all of the required training. Additionally, the surgical closure was not performed as described in the Animal Protocol. Some of the mice had not been transferred to the correct Animal Protocol prior to the surgeries being conducted. All mice were euthanized.

The IACUC Office was promptly notified of the incident and the PI contacted.

October 31, 2019: The Attending Veterinarian, IACUC Chair, and Director of the IACUC Office met with the PI and lab manager to discuss the incident and corrective measures. The PI and lab manager were informed that the IACUC Training and Compliance Manager would schedule a meeting with the lab member upon that member's return to the lab.

November 12, 2019: The IACUC Training and Compliance Manager met with the lab member to provide retraining on all aspects of the event. Before the lab member is allowed to do surgery, a strict step-wise training process will be instituted with each step being observed and competency confirmed by the ITCM and/or OAR veterinary staff.

November 13, 2019: The IACUC members discussed the incident at a convened meeting and voted to report to the appropriate agencies.

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

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

From: OLAW [

OLAW Division of Compliance Oversight (NIH/OD) Monday, November 25, 2019 6:30 AM

Sent: Monday, November 25

To: IACUC

Cc: OLAW Division of Compliance Oversight (NIH/OD)

**Subject:** RE: Report of non-compliance incident

Thank you for these reports, (b) (6) We will send a response soon.

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

From: IACUC <iacuc@uiowa.edu>

Sent: Friday, November 22, 2019 4:53 PM

To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>

Cc: accredit@aaalac.org

Subject: Report of non-compliance incident

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

Thank you, (b) (6)

(b) (6)