



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 3R)

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 the cause of death of the two rats is believed to be due to swelling and inflammation as the nature of the location of stereotaxic injection is associated with potential mortality. The PI and laboratory staff followed all post-procedural monitoring and are well versed in identifying post-surgical complications and methods to report concerns to veterinary staff. The animals were found dead without prior signs of illness or ability to intervene. The laboratory is working with veterinary staff to refine the surgical approach and identify mortality associated with the procedure in addition to amending the protocol to include anti-inflammatory agents to reduce brain swelling.

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
Iowa 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 3R.

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

- 1) What was the cause of death of two rats found dead in their cage?
 - By nature of the location of the stereotaxic injection there is potential mortality associated with the procedure. It is believed that swelling and inflammation at the site likely contributed to the deaths of these animals.
- 2) Was the PI and the laboratory staff members retrained to recognize post-surgical complications, post-procedural monitoring, and mechanisms of reporting clinical concerns to veterinary staff?
 - The PI and laboratory members followed all appropriate post-procedural monitoring and are well versed in identifying post-surgical complications, including mechanisms for reporting to veterinary staff. However, even with appropriate monitoring the animals were found dead without prior signs of illness and ability to intervene.
- 3) How will the corrective actions as described prevent animal death?
 - The lab is working closely with veterinary staff to refine the surgical approach as well as identify associated mortality with the procedure. Additionally, the protocol has been amended to include anti-inflammatory agents to help potential brain swelling that could lead to mortality and reduce post-surgical survival.

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

Sincerely,

(b) (6)

Jennifer Lassner
Institutional Official
Senior Assistant Vice President for Research



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Facsimile: (301) 402-7065

December 12, 2019

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

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 29, 2019, an animal care technician found two dead rats in a cage and upon investigation, a lab member was found to have performed stereotaxic surgery on four animals. The type of surgery was approved in the protocol however the specific surgical approach was not approved. The study is supported by PHS funding.

As a corrective measure, on November 7, 2019 the IACUC Training and Compliance Manager met with the lab member to provide retraining. The lab was also required to submit an amendment describing the alternate surgical approach and the clinical veterinarian will provide consultation and advise on the technique.

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 requests further information as follows:

- What was the cause of death of two rats found dead in their cage?
- Was the PI and laboratory staff members retrained to recognize post-surgical complications, post-procedure monitoring and mechanisms of reporting clinical concerns to veterinary staff?
- How will the corrective actions as described prevent animal death?

We appreciate being informed of this matter and look forward to your responses to the additional information request by **January 31, 2020**. 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



43021-3R

**Office of the Vice President
for Research**

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

November 22, 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 rats. The University of Iowa PHS Assurance Number is D16-00009 (A3021-01). The grant number affected is HL139521.

October 29, 2019: An animal care technician found two rats dead in the cage. Upon investigation, a lab member was found to have performed stereotaxic surgery on four animals. Although the type of surgery was approved in the Animal Protocol, the specific surgical approach used was not.

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

November 7, 2019: The IACUC Training and Compliance Manager met with the lab member to provide retraining. The lab was required to submit the appropriate amendment to describe the alternative surgical approach that may be used for the stereotaxic surgery. The lab will consult with the clinical veterinarian for advice on the technique.

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