



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) 480-3387

January 24, 2022

Re: Animal Welfare Assurance
#A3021-01 (OLAW Case 4W]

Ms. Jennifer Lassner
Associate 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 20, 2021 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals within the animal care and use program at the University of Iowa. According to the information provided, OLAW understands that 13 mice were injected with an experimental agent. The agent was approved on the protocol, but it was administered via an unapproved route and to an unapproved cohort age. The mice were weaned two weeks after the agent was administered. In the days following weaning, nine of the animals were found dead and one was euthanized due to ill health. Necropsies were performed but no definitive cause of death was determined. The mice involved in this incident were supported by NIH funding.

Corrective and preventive measures included retraining of the responsible laboratory staff. In addition, an amendment was submitted to include the route of administration for the agent and the age range of animals to be used. A lower dose range and supportive care was also included in the amendment to ensure appropriate hydration of newly weaned animals on this experiment.

OLAW appreciates the consideration of this matter by the University of Iowa which was consistent with the philosophy of institutional self-regulation. Based on the information provided, OLAW is satisfied that appropriate actions have been taken to investigate this incident and prevent recurrence. We appreciate being informed of this matter and find no cause for further action by this office.

Sincerely,

Robyn M. Engel - Digitally signed by Robyn M.
Engel-S
S
Date: 2022.01.24 08:26:12 -05'00'

Robyn M. Engel, DVM
Animal Welfare Program Specialist
Office of Laboratory Animal Welfare

CC: IACUC contact



**Office of the Vice
President for Research**

University of Iowa
2660 University Capitol Centre
Iowa City, Iowa 52242
319-335-2119
research.uiowa.edu

December 20, 2021

Brent Morse, DVM
Director, Division of Compliance and Oversight
Office of Laboratory Animal Welfare (OLAW)
National Institutes of Health
6700B Rockledge Drive
Suite 2500, MSC 6910
Bethesda, MD 20892

Dear Dr. Morse:

This letter is to report an incident involving mice. The University of Iowa PHS Assurance Number is D16-00009 (A3021-01). The lab involved was internally awarded a portion of funds from grant number TR002536.

November 5, 2021: A lab was found to have injected an approved agent, but the administration occurred through an unapproved route and cohort age. Just over two weeks later these thirteen mice were weaned. Nine of the animals were found unexpectedly dead in the cage over a three-day period of 11/25-11/28. On 12/1, one of the remaining mice was found in ill health and the veterinary staff consulted. Euthanasia was recommended and performed by the lab. Veterinary staff performed necropsy and the collaborating lab was consulted regarding their expertise with the administration of the agent. Cause of death could not be definitively determined. The remaining three animals were found to be in good health.

The IACUC Office was promptly notified. The Senior Compliance and Education Specialist (SCES) contacted the PI and lab member to discuss the incident and retraining was provided. An amendment was submitted to include the route of administration for the agent and the age range of animals to be used. Additionally, a lower dose range and supportive care was included in the amendment to ensure appropriate hydration of newly weaned animals on this experiment.

December 8, 2021: The IACUC members discussed the incident at a convened meeting and voted to report to the appropriate agencies.

I have reviewed the event and believe it was appropriately managed and fully addressed. If you have any questions pertaining to this report, please contact me.

Sincerely,

(b) (6)

Jennifer Lassner
Institutional Official
Associate Vice President for Research

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, December 22, 2021 7:12 AM
To: IACUC
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Report of non-compliance incident

Thank you for these reports. We will send responses soon.

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

From: IACUC <iacuc@uiowa.edu>
Sent: Monday, December 20, 2021 1:17 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: accredit@aaalac.org
Subject: [EXTERNAL] Report of non-compliance incident

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and are confident the content is safe.

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

Thank you,

(b) (6)

