

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

April 19, 2022

Re: Animal Welfare Assurance #A3021-01 (OLAW Case 5E]

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 April 15, 2022 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of Iowa. This letter had not been preceded by a preliminary report to OLAW. According to the information provided, this Office understands that the University of Iowa Animal Care and Use Committee (ACUC) determined that instances of noncompliance occurred with respect to: failure to adhere to the IACUC-approved protocol and the conduct of animal activities without prior IACUC review and approval. The final report states on March 12, 2022, it was discovered that a laboratory administered an experimental agent using an unapproved route of administration, failed to label cages for a hazard, and performed an unapproved surgical procedure. Three mice were found dead and 3 additional mice were identified with abnormal abdomens based on palpation. Euthanasia was necessary for the 3 additional mice. Also, an additional mouse was determined to be unaffected, but the lab elected to euthanize the animal.

In response to the incident, the lab member was retrained on how to verify protocol information and proper cage labeling for hazards. The lab was advised to submit an amendment and once approved, to contact the veterinary staff and/or the IACUC Senior Compliance and Education Specialist for further training on techniques as needed. The report states the amendment is currently under review and the IACUC voted the matter reportable at a convened meeting.

It is noted that this research is supported by PHS funding. Based on its assessment of this explanation, OLAW understands that the University of Iowa has implemented appropriate measures to correct and prevent recurrences of these problems and is now compliant with provisions of the PHS Policy.

We appreciate being informed of these matters and find no cause for further action by this Office.

Sincerely,

Jacquelyn T. Tubbs -S Date: 2022,04.19 15:12:29 -04'00'

Digitally signed by Jacquelyn Ta

Jacquelyn Tubbs, DVM, DACLAM Senior Animal Welfare Program Specialist Division of Compliance Oversight Office of Laboratory Animal Welfare

cc: IACUC Contact



7 A3021-5E

Office of the Vice President for Research

University of Iowa 2660 University Capitol Centre Iowa City, Iowa 52242 (b) (6) research.ulowa.edu

April 15, 2022

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 grant number affected is DE028527.

March 12, 2022: A lab was found to have administered an experimental agent by an unapproved route (intraperitoneal), did not appropriately label cages for a hazard, and performed an unapproved surgical procedure (approved in another of their Animal Protocols). Three mice were found dead in the cage. Three additional mice had abdomens that palpated abnormally. Euthanasia was required for these three animals. An additional mouse was unaffected; the lab elected to euthanize it.

The IACUC Office was promptly notified and PI informed of the incident. The lab member was retrained in verifying protocol information, following only approved procedures, and proper cage labeling for hazards. Additionally, the lab was instructed to submit an amendment and once approved to contact the veterinary staff and/or the IACUC Senior Compliance and Education Specialist for further training on techniques as needed. An amendment to the Animal Protocol was submitted and is under review.

April 13, 2022: 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]

Thank you for these reports,

From: Sent:

To:

Cc:

Subject:

Thank you,

	Axel Wolff, M.S., D.V.M.
	Deputy Director, OLAW
	From: ACUC <iacuc@uiowa.edu></iacuc@uiowa.edu>
	Sent: Friday, April 15, 2022 1:51 PM
	To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov></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.
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	Please see attached reports of non-compliance at the University of Iowa.
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OLAW Division of Compliance Oversight (NIH/OD)

OLAW Division of Compliance Oversight (NIH/OD)

(b) (6) We will send responses soon.

Monday, April 18, 2022 7:22 AM

RE: Report of non-compliance incident

IACUC

(b) (6)