



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

July 12, 2021

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

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 June 11, 2021 letter in response to OLAW's June 11, 2021 request for information regarding an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at The University of Iowa. OLAW understands that all 13 mice detailed in the report were found dead in the cage which lead to the investigation. The agent that was administered was found to be the most likely cause of mortality however it was found to be used without toxicity by the supplier per published literature. The laboratory is working with veterinary staff to refine and evaluate further use of the agent in the lab's genetically modified animals.

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 and to attempt to prevent recurrence. OLAW expects continuing post-approval monitoring to prevent recurrence of this non-compliance and potential associated animal welfare concern. We appreciate being informed of this matter and please contact us with any further questions or concerns

Sincerely,

Nicole L. Lukovsky- akhsanov -S  
Digitally signed by Nicole L.  
Lukovsky-akhsanov -S  
Date: 2021.07.12 07:29:02 -04'00'

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**

University of Iowa  
2660 University Capitol Centre  
Iowa City, Iowa 52242  
319-335-2119  
[research.uiowa.edu](http://research.uiowa.edu)

June 11, 2021

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:

This letter is to provide additional information, as requested, for case UI 3021-4S.

The original report indicated that four cages (13 mice) were involved in the non-compliance. Your interim response letter dated June 11, 2021 requests information on the disposition of the "remaining four animals." However, no information on the disposition of any of the 13 mice was detailed in our report. All mice were found dead in the cage which led to the investigation of the event and determination of this non-compliance. The agent that was injected is the most likely cause. It was reviewed and found to have been used successfully, without toxicity, by the supplier (i.e., found in published literature). It appears the agent caused toxicity in this lab's genetically modified mice. The lab is working closely with veterinary staff to refine and evaluate further use of this agent in their particular animals.

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

Sincerely,

(b) (6)

A large rectangular area of the document is redacted with a solid grey box, obscuring the signature of Jennifer Lassner.

Jennifer Lassner  
Institutional Official  
Associate Vice President for Research

## Walker, Keri (NIH/OD) [E]

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**From:** IACUC <iacuc@uiowa.edu>  
**Sent:** Monday, June 14, 2021 3:00 PM  
**To:** Walker, Keri (NIH/OD) [E]  
**Cc:** Lassner, Jennifer L; (b) (6)  
**Subject:** RE: OLAW Case A3021-4S  
**Attachments:** NIH Case UI 3021-4S follow up.pdf

**Follow Up Flag:** Follow up  
**Flag Status:** Flagged

Hello Keri,

Please find attached our response to Dr. Lukovsky-Akhsanov's letter.

Thank you,

(b) (6)

**From:** Walker, Keri (NIH/OD) [E] <keri.walker@nih.gov>  
**Sent:** Friday, June 11, 2021 12:35 PM  
**To:** Lassner, Jennifer L <jennifer-lassner@uiowa.edu>  
**Cc:** (b) (6) IACUC <iacuc@uiowa.edu>  
**Subject:** OLAW Case A3021-4S

Dear Ms. Lassner,

Attached please find Dr. Lukovsky-Akhsanov's *interim* response to OLAW Case A3021-4S.

If you have any questions, feel free to contact us by phone or by e-mail.

Regards,  
Keri

*Keri Walker  
Program Analyst  
Division of Compliance Oversight  
Office of Laboratory Animal Welfare  
National Institutes of Health  
6700B Rockledge Dr., Suite 2500  
Bethesda, MD 20892  
301-435-2390  
[keri.walker@nih.gov](mailto:keri.walker@nih.gov)*



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June 11, 2021

Re: Animal Welfare Assurance  
#A3021-01 (OLAW Case 4S)

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 May 14, 2021 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 April 10, 2021, a lab member injected 13 mice with unapproved treatment agents however the agents were approved on another one of the lab's approved protocols. The study was PHS funded.

As a corrective measure, the IACUC Training and Compliance Manager met with the lab member to provide retraining and discussed the matter with the Principal Investigator. An amendment to the protocol was submitted and is under IACUC review.

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 the following information:

- Please provide information regarding direct animal welfare concerns related to noncompliance including any required medical interventions (e.g. treatment, euthanasia) and animal disposition for the remaining four animals.

We look forward to your responses to the to the additional information request by **July 2, 2021**. Please contact us with any further questions or concerns

Sincerely,

Nicole L. Lukovsky-  
akhsanov -S

Digitally signed by Nicole L.  
Lukovsky-akhsanov -S  
Date: 2021.06.11 11:48:41  
-04'00'

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**

University of Iowa  
2660 University Capitol Centre  
Iowa City, Iowa 52242  
319-335-2119  
[research.uiowa.edu](http://research.uiowa.edu)

May 14, 2021

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 CA099908.

April 10, 2021: A lab member was found to have injected mice with unapproved tumor treatment agents (four cages with 13 total mice), resulting in an unapproved procedure. The agents are approved on another of the lab's approved Animal Protocols.

The IACUC Office was promptly notified. The IACUC Training and Compliance Manager met with the lab member to provide retraining. S/he also discussed the matter with the PI and recommendations were made to the PI to amend the protocol, or to otherwise ensure proper transfer of mice to the appropriate protocol. The amendment has been submitted and is under IACUC review.

May 12, 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)

A large grey rectangular box redacting the signature of Jennifer Lassner.

Jennifer Lassner  
Institutional Official  
Associate Vice President for Research

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

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Monday, May 17, 2021 10:06 AM  
**To:** IACUC  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: Report of non-compliance incident

Thank you for this report. We will respond soon.

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

**From:** IACUC <iacuc@uiowa.edu>  
**Sent:** Monday, May 17, 2021 9:41 AM  
**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 a report of non-compliance at the University of Iowa.

Thank you,

(b) (6)

