



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

November 18, 2021

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

Dr. Martin J. Scholtz
Vice President for Research
The University of Iowa
Office for the Vice President for Research
2660 University Capitol Centre
Iowa City, Iowa 52242

Dear Dr. Scholtz,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your revised final letter submitted on November 8, 2021 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 August 3, 2021, a review of a journal publication determined that the lab performed an unapproved procedure and subsequently it was determined that a second publication also described the unapproved procedures. Both the agent and the route of administration were approved on the protocol however the pairing of the route with the agent was unapproved. A total of 840 mice were used and there were no known animal welfare impacts due to the non-compliance. All mice were euthanized at the completion of studies. The studies were PHS funded.

As a corrective measure, lab retraining, and protocol amendments were made as required. The Principal Investigator informed the journals regarding revision of statements that all procedures were IACUC approved. One journal has responded with nothing further requested and the response from the second journal is still pending after two notifications were provided to them.

OLAW appreciates the prompt consideration of this matter by The University of Iowa which is consistent with the philosophy of institutional self-regulation. OLAW expects continuing post-approval monitoring to prevent recurrence of this non-compliance and potential associated animal welfare concerns. Based on the information provided, OLAW is satisfied that appropriate steps have been taken to investigate this incident and to attempt to prevent recurrence.

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
Dr. Erik Stemmy, Program Officer, NIAID
Ms. Emily Linde, Chief Grant Manager, NIAID



**Office of the Vice
President for Research**

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

September 16, 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 grant number affected is P01 AI060699.

August 3, 2021: Following review of a journal publication it was determined that the lab performed an unapproved procedure. It was subsequently determined that a second publication also described the unapproved procedure. Both the agent and route of administration were approved in the Animal Protocol; however, the pairing of the route with the agent for this particular procedure was not approved. A combined total of about 840 animals were used. There were no known animal welfare impacts due to the non-compliance. All mice were euthanized at the completion of the studies.

The IACUC Office was promptly notified. Lab retraining occurred and proper amendments to the Animal Protocol were made.

September 8, 2021: The IACUC members discussed the incident at a convened meeting and voted to report to the appropriate agencies. Additionally, the PI has informed the journals regarding revision of statements that all procedures were approved by the IACUC. Response from one journal has been received (nothing further required from them). No response has been received from the second journal after two notifications to them.

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

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, September 17, 2021 8:06 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 responses soon.

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

From: IACUC <iacuc@uiowa.edu>
Sent: Thursday, September 16, 2021 4:29 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)