

## 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 5, 2022

Re: Animal Welfare Assurance A3464-01 [OLAW Case 11S]

Sally Thompson-Iritani, DVM, PhD, CPIA, CCFP Associate Vice Provost University of Washington 4000 15<sup>th</sup> Ave NE Box 351202 Seattle, WA 98195-6355

Dear Dr. Thompson-Iritani,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your March 28, 2022 letter reporting a noncompliance with the PHS Policy on the Humane Care and Use of Laboratory Animals at the University of Washington. Your letter supplements the information in the prompt preliminary telephone report on January 21, 2022. According to the information provided, it is understood that on January 14, 2022, it was self-reported that between December 17-23, 2021, twelve rats were given methylprednisolone by tail vein injection. The protocol was approved for administration of dexamethasone, by intraperitoneal injection. An additional 18 rats received intravenous (IV) saline as a control. The IV route was also not approved on the IACUC protocol. The animals in question were not supported by PHS funds.

Corrective and preventive actions: the group self-initiated a plan to train, or retrain, all group members on how to access and review the IACUC protocol in the university's electronic protocol management system, as well as a process for having the lab manager double-check that experiments are approved before they are initiated. An amendment to the protocol was promptly submitted. These measures were accepted and approved by the IACUC.

OLAW appreciates being notified by the University of Washington of this issue. Your reporting of this incident is consistent with the provisions of the PHS Policy on Humane Care and Use of Laboratory Animals for institutional self-monitoring, self-reporting, and self-correction. Although this activity was not PHS funded, the application of the expectations of the PHS Policy across the animal care and use program reduces any potential appearance of a double standard. We find no cause for further action by this office.

Sincerely,

Brent C. Morse -S Solute: 2022.04.07 68:49:55 -04'00'
Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC contact

A3464-115



28 March 2022

Dr. Brent Morse <u>olawdco@od.nih.gov</u>
Office of Laboratory Animal Welfare NIH
Rockledge 1, Suite 360, MSC 7982
6705 Rockledge Drive
Bethesda, MD 20892

Re: D16-00292 (A3464-01), Administration of Unapproved Substance

Dear Dr. Morse:

This is a final report on an adverse event reported to OLAW by 6) in a telephone call on 1/21/22.

On January 14, 2022, it was self-reported by a group that between December 17-23, 2021, 12 rats were given a substance that was not approved on their IACUC protocol. The protocol was approved for administration of a steroid, dexamethasone, by intraperitoneal injection, but a different steroid, methylprednisolone, was instead given by tail vein injection. An additional 18 rats received intravenous (IV) saline as a control. The IV route was also not approved on the IACUC protocol.

The group self-initiated a plan to train, or retrain, all group members on how to access and review the IACUC protocol in the university's electronic protocol management system, as well as a process for having the lab manager double-check that experiments are approved before they are initiated. An amendment to the protocol was promptly submitted.

The IACUC reviewed the incident at its March meeting and found no further action necessary (considers the case closed). The animals in question were not supported by PHS funds.

If you have questions regarding this situation or require additional information, please don't hesitate to contact me.

Sincerely,

(b) (6)

Sally Thompson-Iritani DVM/PhD, CPIA, CCFP Institutional Official Asst. Vice Provost, Animal Care, Outreach & 3Rs Clinical Associate Professor, DEOHS, SPH

Office of Research

Cc: Jane Sullivan

(b) (6)

accredit@aaalac.org

UNIVERSITY of WASHINGTON

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

From:

OLAW Division of Compliance Oversight (NIH/OD)

Sent:

Wednesday, March 30, 2022 7:32 AM

To:

Cc:

OLAW Division of Compliance Oversight (NIH/OD)

Subject:

RE: Final report of 3 non-compliant events

Thank you for these reports,

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

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

From:

(b) (6)

Sent: Monday, March 28, 2022 4:44 PM

To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>

Cc: Jane Sullivan <jmsull@uw.edu>; Sally Thompson-Iritani <sti2@uw.edu>; accredit@aaalac.org;

(b)(6)

Subject: [EXTERNAL] RE: Final report of 3 non-compliant events

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 the attached final report of 3 noncompliant events at the University of Washington. Please let me know if you have any questions.

(b) (6)



## **Initial Report of Noncompliance**

Date: 1/21/22 Time: 600
Name of Person reporting:  Telephone #:  Fax #:  Email:
Name of Institution: Assurance number:  1 3 464
Did incident involve PHS funded activity? Funding component: Was funding component contacted (if necessary):
What happened?  12 rates got soulistance most listed on protecul.
Species involved: Personnel involved: Dates and times: Animal deaths:
Projected plan and schedule for correction/prevention (if known):
Seyreported to I neve
Projected submission to OLAW of final report from Institutional Official:
OFFICE USE ONLY Case #