



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

December 11, 2023

Re: Animal Welfare Assurance
A3245-01 (OLAW Case 5A)

Frederick H. Epstein, Ph.D.
Professor & Interim Vice President for Research
University of Virginia
P.O. Box 400301
136 Hospital Drive
Charlottesville VA 22904

Dear Dr. Epstein,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your October 24, 2023 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 Virginia. Your letter supplemented the information contained in an initial email report to this office on September 28, 2023. According to the information provided, OLAW understands that five rooms housing mice and rats were not checked by the animal caretaker on one day of a weekend. The responsible caretaker was experienced but was substituting in the facility. The issue was discovered on the afternoon of the same day by the veterinary technician. The technician reported the oversight to a weekend supervisor but neither the technician nor the supervisor performed the husbandry duties. The check was performed the next day and no animal health issues were noted. The IACUC considered this to be a programmatic issue involving failure to maintain appropriate animal-related records.

Corrective and preventive measures were initiated. The Attending Veterinarian and husbandry management team counseled the husbandry and veterinary staff involved in the incident regarding the importance of teamwork and providing animal care duties when necessary. The group was retrained on daily husbandry duties and the importance of completing documentation. In the future, the senior caretaker will check the documentation for each animal room near the end of the shift to ensure that all tasks have been performed and documented.

OLAW appreciates the consideration of this matter by the University of Virginia, 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: 2023.12.11 10:52:53 -05'00'

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

cc: IACUC contact

Ware, Teagan (NIH/OD) [E]

A3245-SA

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Tuesday, October 24, 2023 11:26 AM
To: (b) (6) OLAW Division of Compliance Oversight (NIH/OD)
Cc: (b) (6) Morse, Brent (NIH/OD) [E]
Subject: RE: Animal Care and User Report - UVA - UVA 2023-F and UVA 2023-G

Hello (b) (6)

Thank you for following up with these two final reports. We will send official responses soon.

Best,
Teagan

Teagan Ware, MS, PMP
Animal Welfare Program Analyst
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health

Phone: 301-435-2390
Email: teagan.ware@nih.gov

Disclaimer: Please note that this message and any of its attachments are intended for the named recipient(s) only and may contain confidential, protected, or privileged information that should not be distributed to unauthorized individuals. If you have received this message in error, please contact the sender.

From: (b) (6)
Sent: Tuesday, October 24, 2023 10:57 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>; Morse, Brent (NIH/OD) [E] <morseb@mail.nih.gov>
Cc: (b) (6)
Subject: [EXTERNAL] Animal Care and User Report - UVA - UVA 2023-F and UVA 2023-G

Dr. Brent Morse, Division Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health RKL 1, Suite 360, MSC 7982
6705 Rockledge Dr., Bethesda, MD

Dr. Morse:

We previously submitted an email notification on two compliance matter, UVA 2023-F (see attached) which was assigned OLAW case number A3245-5A and UVA 2023-G. which was assigned OLAW case number 3245-5B (see attached). Our email report and the OLAW response is attached.

Due to the nature and the timing of these issues as described in the notification email, that email contained less than the usual preliminary report information but indicated that a final report would be submitted.

As we indicated, these two incidents were reported to the IACUC by the UVA Attending Veterinarian who also serves as the director of the UVA animal husbandry unit. At the time of this report, the AV summarized the incidents and described the corrective actions taken to prevent recurrence.

The IACUC reviewed the incidents and the corrective actions and has determined that this matter is now resolved to their satisfaction.

I have reviewed their final reports and I agree with their recommendations.

(b) (6)

University of Virginia
Animal Care and Use Compliance Report
PHS Assurance # A3245-01

The Institutional Animal Care and Use Committee (IACUC) discovered the following compliance issue. An email notification was sent to the OLAW Division of Compliance Oversight by the Director of the Office of Animal Welfare, and Devora McCoy, Program Analyst, acknowledged receipt. Due to the timing of the investigation and resolution, the usual preliminary email notification to OLAW was not feasible. It was understood that a full report would be submitted by the IO. This document is a summary of the incident, actions taken, and final resolution.

UVA Case #: 2023-F
OLAW Case #: A3245-5A

| | |
|--|--|
| Nature of Incident(s): | Failure to maintain appropriate animal-related records (husbandry) |
| Summary of Incident: | During a monthly Institutional Animal Care and Use Committee (IACUC) meeting, the Attending Veterinarian self-reported that five rooms in one vivarium were inadvertently overlooked on one day of a weekend. The rooms were assigned to an experienced animal caretaker familiar with the animal facility. The caretaker ordinarily worked in a different facility but was substituting in the facility over the weekend based on their previous work in the facility. The issue was discovered on the same day of occurrence by a veterinary technician in the afternoon. The veterinary technician reported the issue to the weekend supervisor; however, the veterinary technician and weekend supervisor failed to perform the duties. The oversight was noted the next day, and upon discovery, the rooms were immediately checked. No animal health issues were noted. The rooms housed mice or rats. |
| Action taken by IACUC: | The IACUC discussed the incident at the next convened meeting and determined that the incident was a significant deficiency due to the failure to maintain appropriate animal-related records. The IACUC considered it a programmatic issue because it had the potential of impacting any animal at the institution (i.e., federally funded, institutionally funded). The Attending Veterinarian provided the corrective actions taken to prevent reoccurrence within the initial report submitted to the IACUC. The IACUC reviewed the corrective actions at the same time as the report. |
| Action taken by Attending Veterinarian: | As part of the initial report, the Attending Veterinarian provided the corrective actions taken to prevent reoccurrence. The Attending Veterinarian and husbandry management team spoke with the husbandry and veterinary staff involved in the incident. All three were counseled on the importance of teamwork and providing animal care duties when necessary, even as back-up to other team members or in cases of emergency. The group was retrained regarding required daily husbandry duties and the importance of completing documentation. In the future, the senior caretaker working in the vivarium on the weekend day will check the documentation for each animal room near the end of the shift to ensure that all tasks have been performed and documented. |

| | | | |
|--|--|---------|--|
| Action taken by IACUC: | The IACUC felt that the AV responded appropriately and no further action was deemed necessary. | | |
| Decision/Resolution: | The IACUC considered the incident resolved. | | |
| Federal Funding: | Considered a programmatic issue | | |
| Notification of Final Disposition: | <input checked="" type="checkbox"/> IO <input checked="" type="checkbox"/> OLAW | | |
| Institutional Official: Dr. Frederick H. Epstein | Date: October 24, 2023 | (b) (6) | |

Ware, Teagan (NIH/OD) [E]

A3245-5A

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, October 2, 2023 10:14 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Notification of Non-Compliance: UVA - #A3245-01 (Case #2023-F, Case #2023-G)

Good morning (b) (6)

Thank you for sending us these preliminary reports and we look forward to receiving the final reports once completed. I have documented the UVA tracking numbers along with our assigned case numbers (added below), so please references either the UVA tracking number or OLAW case number when sending the final reports.

Thanks,
Devora

Devora McCoy, BS, MBA ([pronunciation](#))
Animal Welfare Program Analyst
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health

Phone: 301-435-2390
Email: devora.mccoy@nih.gov

***Disclaimer:** Please note that this message and any of its attachments are intended for the named recipient(s) only and may contain confidential, protected, or privileged information that should not be distributed to unauthorized individuals. If you have received this message in error, please contact the sender.*

From: (b) (6)
Sent: Thursday, September 28, 2023 5:58 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>; Wolff, Axel (NIH/OD) [E] <wolffa@od.nih.gov>
Cc: (b) (6)
Subject: [EXTERNAL] Notification of Non-Compliance: UVA - #A3245-01 (Case #2023-F, Case #2023-G)

Dear OLAW Division of Compliance Oversight,

This is to provide notification that the University of Virginia IACUC (PHS Assurance #A3245-01) identified two significant deficiencies related to rodent care and transport. The UVA tracking numbers are listed below.

- **(OLAW case number A3245-5A)- 2023-F:** failure to maintain appropriate animal-related husbandry records. The animal husbandry records were incomplete for one weekend day in several rodent rooms. No animal health or welfare issues were noted.
- **(OLAW case number A3245-5B)- 2023-G:** condition that jeopardized the health of animals following internal animal transport

The two incidents were self-reported separately to the IACUC by the Attending Veterinarian, who also serves as the director of the animal husbandry unit. Within each report, the Attending Veterinarian summarized the incident and provided the corrective actions taken to prevent reoccurrence. At the time of reporting, the IACUC determined that adequate measures were taken and determined that the issues were resolved upon reporting. Both were determined to be programmatic deficiencies and reportable to the OLAW Division of Compliance Oversight; however, due to the timing of the investigation and resolution, a preliminary email notification to the OLAW Division of Compliance Oversight was not feasible. The IO will send a separate final compliance report for each incident and will reference this communication for context.

Should you have any questions or concerns, please do not hesitate to contact me.

Sincerely,

(b) (6)