



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

August 11, 2022

Re: Animal Welfare Assurance
#A3245-01 [OLAW Case 4M]

Dr. Melur Ramasubramanian
Vice President for Research
University of Virginia
P.O. Box 400301
Charlottesville, VA 22904

Dear Dr. Ramasubramanian,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your August 1, 2022 Animal Welfare Compliance Report detailing an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of Virginia following up on an initial May 3, 2022 notification by email.

According to the information provided, this Office understands that the University of Virginia Animal Care and Use Committee (ACUC) determined that instances of noncompliance occurred with respect to unapproved deviations from the standards of housing and husbandry practices as per the *Guide for the Care and Use of Laboratory Animals*. The report states the Attending Veterinarian (AV) notified the Office of Animal Welfare (OAW) of issues identified during a routine visit to the vivarium and as reported by the vivarium assistant supervisor. It is stated all caging for tree shrews was being sanitized once per month instead of once every 2wk. Originally, the colony consisted of breeding pairs and the protocol was approved for non-standard husbandry (cage sanitation once monthly), specifically for breeding pairs and nursing females. The colony now includes juveniles and animals on study and the non-standard husbandry practices were applied to these animals as well. The AV stated there had been no animal health issues related to the reduced frequency of cage sanitation. The vivarium supervisor stated they were unaware cage sanitation should have occurred once every 2wk. The Principal Investigator (PI) was informed all non-breeders, juveniles and study animals would be sanitized every 2wk. Ultimately, the IACUC reviewed and approved the non-standard husbandry practices for all animals (i.e., sanitation monthly) until additional space could be obtained to separate breeding and nursing animals from the remaining colony.

The report states the population of animals exceeded the housing capacity available for the tree shrews, and the vivarium supervisor used alternate caging for some animals. Initially, the alternate caging was utilized briefly while standard caging was processed through cage wash. However, as the population grew, juveniles and some females with young animals were housed in the alternate caging for several months. Ultimately, the PI decreased the colony size, and it is understood the square footage of the standard and alternate caging is the same. Again, the AV stated there were no reports of animal health issues associated with the use of the alternate caging. The IACUC and AV reviewed animal housing parameters and colony management plans during the interim while obtaining additional caging and additional space to accommodate the new caging. The PI was notified the colony must be maintained at a level that the caging could accommodate, and animal density must be acceptable. After review, the committee was satisfied with the colony management and will reassess the room and caging necessities of the colony upon receipt of additional caging.

It is stated the vivarium supervisor kept animals in nest boxes for ~30min while the alternate caging was sanitized, and then the animals were returned to clean caging. The vivarium supervisor stated they were unaware the IACUC policy did not permit animals to be physically restrained for >5min without prior protocol approval. No animal health issues were reported with use of nest boxes for prolonged periods of time. The supervisor was instructed to not use nest boxes in this manner. Also, the vivarium supervisor was sent a Letter of Counseling and warning that similar actions in the future without seeking consultation, especially from the AV, would result in disciplinary action.

The IACUC held a special convened meeting to discuss housing guideline differences between the *Guide* and Animal Welfare Regulations (AWRs) to expedite the purchase of additional caging. The IACUC voted to approve a deviation from the *Guide* cage size recommendations and will enforce the cage size requirements as stated in the AWRs. It is understood the committee discussed the issues during monthly meetings and reviewed follow-up correspondence from the PI to fully address each issue identified and ensure resolution. It is understood the IACUC accepted the final resolution submitted by the PI and AV and no additional action was required.

OLAW advises/expects that proper caging be made available in advance of an increase in animal population. Based on the information provided, the Office of Laboratory Animal Welfare (OLAW) is satisfied that appropriate actions have been taken to correct and prevent recurrence of the noncompliance.

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

Sincerely,

Jacquelyn T.

Digitally signed by Jacquelyn T.

Tubbs -S

Tubbs -S
Date: 2022.08.11 14:12:47 -04'00'

Jacquelyn Tubbs, DVM, DACLAM

Senior Animal Welfare Program Specialist

Division of Compliance Oversight

Office of Laboratory Animal Welfare

cc: IACUC Contact

Robert M. Gibbens, DVM, Director, Animal Welfare Operations

McCoy, Devora (NIH/OD) [E]

From: McCoy, Devora (NIH/OD) [E]
Sent: Thursday, August 11, 2022 3:59 PM
To: acuc@virginia.edu
Cc: OLAW Division of Compliance Oversight (NIH/OD); [REDACTED] (b) (6)
Robert.m.gibbens@usda.gov
Subject: OLAW Case A3245-4M
Attachments: A3245-4M.pdf

Good afternoon Dr. Ramassubramanian,

Attached please find Dr. Tubbs' final response to OLAW Case A3245-4M. If you have any questions, feel free to contact us by phone or by e-mail.

Best,
Devora

Devora McCoy, BS, MBA
Program Analyst
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
301-435-2390

University of Virginia
Animal Welfare Compliance Report
PHS Assurance # A3245-01

The Institutional Animal Care and Use Committee identified the following compliance issue while performing an assessment in the vivaria. A preliminary email notification was sent to the OLAW Division of Compliance Oversight by [REDACTED] ^{(b) (6)} Dr. Axel Wolff acknowledged receipt. It was understood that a full report would be submitted following an IACUC investigation. This document is a summary of the incident, actions taken, and final resolution.

UVA Compliance Case #: 2022-C

Nature of Incident(s):	Unapproved deviations from the standards of housing and husbandry practices as outlined in the <i>Guide for the Care and Use of Laboratory Animals</i> (tree shrews)
Summary of Incident: <i>(contains a description of each issue noted and actions taken by the PI, AV, and IACUC)</i>	<p>The Attending Veterinarian (AV) self-reported to the Office of Animal Welfare (OAW) issues noted during a routine visit to the vivarium and reported to the AV by the vivarium assistant supervisor. The issues were closely related and reported, discussed, and resolved simultaneously.</p> <p>All tree shrew animal caging was being sanitized once per month instead of once every two weeks. Initially, the colony only contained breeding pairs and the protocol was approved for non-standard husbandry, specifically for breeding pairs and nursing females - cage sanitation occurred once monthly. The colony had since expanded to include juveniles and animals on study; however, the non-standard husbandry practices were being applied to the non-breeding animals. The vivarium supervisor indicated that they were unaware that non-breeding/nursing cages should have been sanitized once every two weeks. According to the AV, there had been no reported animal health issues associated with the delay in sanitation of the cages. Corrective Actions: The PI was immediately notified that all cages containing non-breeders, juveniles, or study animals would be sanitized once every two weeks. Due to the small size of the animal room, the PI immediately submitted a protocol modification requesting non-standard husbandry for the entire room due to the anticipated increase in noise and activity levels that would accompany more frequent sanitation. There was concern that the breeders and nursing dams would be affected. The IACUC reviewed and approved the non-standard husbandry practices for all animals (i.e., sanitation monthly) until additional space could be obtained to separate breeding and nursing animals from the remaining colony.</p> <p>The population of animals increased beyond the housing capacity available for the species. Once capacity had been exceeded, the vivarium supervisor used alternate caging to house some of the animals. Initially the alternate cages were used to briefly contain the animals while the standard caging was being processed through cage wash, and then the animals were returned to the clean standard cage. However, when the population grew and the standard caging was completely occupied, the vivarium supervisor began housing juveniles and some females with young in the alternate caging for several months as the animal population fluctuated. The vivarium supervisor notified the PI of the population growth and possible compliance and animal welfare issues associated</p>

with housing animals in alternate caging. The PI reduced the colony size. The square footage of the standard and alternate caging were the same. According to the AV, while housed in the alternate caging the animals were able to express natural postures and make postural adjustments without touching the enclosure walls or ceilings. According to the AV, there were no reported animal health issues noted associated with the use of the alternate caging. **Corrective Actions:** The Clinical Veterinarian immediately met with the PIs and discussed the lack of caging and the immediate need for obtaining additional caging. The PIs were provided caging quotes and the AV assisted locating funds for the caging purchase. Due to the extended period of time for obtaining the new caging, the IACUC and AV discussed animal housing parameters and colony management plans during the interim while obtaining additional caging and additional room space to accommodate the new caging. The IACUC informed the PI that the colony must be maintained at a level that the caging would accommodate and the animals must be maintained at an acceptable density. The IACUC voted to approve a deviation from the *Guide* cage size recommendations and will enforce the cage size requirements as stated in the Animal Welfare Regulations. The IACUC explicitly provided the density/cage given the current caging available and told to comply. The PI provided written confirmation with respect to population reduction, cage purchases, protocol modifications (for single housing), and improvements to the oversight of the colony. Additionally, the IACUC examined the internal and external need for these animals with respect to the PI's breeding colony production. The PI provided an outline of demand for the animals being bred: researcher need, replacing breeders, and external demand. The IACUC was satisfied with the management of the colony and required no further actions. Upon receipt of the additional caging, the IACUC will re-evaluate the room and cage needs of the colony.

During the time period when alternate caging was used to house animals, the vivarium supervisor maintained animals in nest boxes for approximately 30 minutes during cage sanitation. The animals were maintained within their nest boxes while the caging was sanitized in cage wash, and once the cages were cleaned, the animals were returned to the clean caging. The vivarium supervisor was unaware that the IACUC policy does not permit animals to be physically restrained for greater than five minutes without prior protocol approval. According to the AV, there were no animal health issue noted associated with the animals being kept in the nest boxes for 30 minutes. **Corrective Actions:** In accordance with IACUC policy, the AV instructed the vivarium supervisor not to use nest boxes in this way. The IACUC sent the AV correspondence describing their concerns involving the vivarium supervisor. The issues noted involved the vivarium supervisor and unapproved deviations or poor decisions made without AV consultation or IACUC review and approval. The vivarium supervisor received a Letter of Counseling and warning that taking similar actions in the future without seeking appropriate consultation would result in disciplinary action.

IACUC Discussion and Resolution:	<p>The IACUC initially discussed the issues at the next convened meeting and determined that it was a significant deficiency because of the unapproved deviations from the <i>Guide</i>. The protocol modifications submitted were immediately reviewed by the IACUC. In order to expedite the purchase of additional caging, the IACUC held a special convened meeting to discuss housing guideline differences between the <i>Guide</i> and Animal Welfare Regulations and voted to approve the deviation from the <i>Guide</i> cage size recommendations and will enforce the cage size requirements as stated in the Animal Welfare Regulations. The IACUC continued to discuss the issues during monthly meetings and requested and then reviewed follow up correspondence from the PI to fully address each issue noted and ensure resolution. The IACUC accepted the final resolution submitted by the PI and AV and no further action was deemed necessary. The issue was considered resolved.</p>
Federal Funding:	1U01NS122040
Notification of Final Disposition:	<input checked="" type="checkbox"/> IO <input checked="" type="checkbox"/> OLAW
Institutional Official: Dr. Melur K. Ramasubramanian	<div style="background-color: #cccccc; width: 100%; height: 20px; display: flex; justify-content: flex-end; align-items: center; padding-right: 5px;">(b) (6)</div> Date: August 1, 2022

McCoy, Devora (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, August 1, 2022 11:15 AM
To: [REDACTED] (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: OLAW Report

Good morning [REDACTED] (b) (6)

Thank you for sending us these reports and we will send an official response soon.

Best,
Devora

Devora McCoy, BS, MBA
Program Analyst
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
301-435-2390

From: [REDACTED] (b) (6)
Sent: Monday, August 1, 2022 10:46 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>; Wolff, Axel (NIH/OD) [E] <wolffa@od.nih.gov>
Cc: [REDACTED] (b) (6)
Subject: [EXTERNAL] OLAW Report

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

Dr. Wolff:

I attach two compliance reports from our IACUC. These are 2022-C and 2022-D.

Preliminary reports were submitted.

Appropriate corrective action has been taken and the IACUC has determined that these matters are now resolved to their satisfaction.

[REDACTED] (b) (6)



Wolff, Axel (NIH/OD) [E]

A3245-4M

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, May 4, 2022 7:33 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: preliminary notification - UVA (Assurance A3245-01). Case 2022-C

Thank you for this preliminary report, (b) (6) We will start a new case file and look forward to receiving the final report from the IO after the IACUC has completed its investigation.

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

From: (b) (6)
Sent: Tuesday, May 3, 2022 5:13 PM
To: Wolff, Axel (NIH/OD) [E] <wolffa@od.nih.gov>; OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: (b) (6)
Subject: [EXTERNAL] preliminary notification - UVA (Assurance A3245-01). Case 2022-C

Dear OLAW Division of Compliance Oversight,

This is to provide preliminary notification that the University of Virginia IACUC (PHS Assurance #A3245-01) identified several possible significant deficiencies within the tree shrew colony. The UVA tracking number is 2022-C.

The issues are currently under investigation and review by the IACUC. We are working towards resolution and will send a separate compliance report once resolved. There appears to be a failure to adhere to the IACUC-approved protocol and unauthorized deviations from the *Guide for the Care and Use of Laboratory Animals* with respect to housing and husbandry practices.

Should you have any questions or concerns prior to receiving our final report, please do not hesitate to contact me.

Sincerely,

(b) (6)