



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

October 18, 2021

Re: Animal Welfare Assurance
A3200-01 [OLAW Case 3M]

Dr. Susan Buskirk
Vice President – Chief Accountability Officer
University of Maryland School of Medicine
620 West Lexington St. (b) (4)
Baltimore, MD 21201-1559

Dear Dr. Buskirk,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your October 11, 2021 letter reporting a serious deviation from the provisions of the *Guide for the Care and Use of Laboratory Animals* at the University of Maryland- Baltimore, following up on an initial telephone report on June 1, 2020. According to the information provided, OLAW understands that Institutional Animal Care and Use Committee (IACUC) standard operating procedures regarding recordkeeping were not followed. Specifically, in a Principal Investigator-managed satellite facility, animal records were falsified, tasks were checked off as having been completed even though the animal caretaker was not on site, and the required daily health checks were not conducted. Due to the laboratory staff actions such as monitoring animals and performing husbandry duties, no adverse effects occurred with the animals.

The corrective actions consisted of the laboratory manager completing health checks and cage changes, and having Human Resources (HR) discipline the animal caretaker responsible. The caretaker's actions were subsequently closely monitored and upon identifying another missed health check, the individual's animal use privileges were revoked. Ongoing veterinary inspections of the facility have not identified any animal welfare problems, which is in part due to the establishment of appropriate quality control procedures by the laboratory staff. The IACUC has raised concerns to the Institutional Official regarding prompt intervention by HR in cases where animal welfare is impacted.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to correct and prevent recurrence of this problem. OLAW concurs with the actions taken by the IACUC to comply with the PHS Policy on Humane Care and Use of Laboratory Animals.

Sincerely,

(b) (6)

Axel Wolff, M.S., D.V.M.
Deputy Director
Office of Laboratory Animal Welfare

cc: IACUC Chair

October 11, 2021

Brent C. Morse, DVM, DACLAM
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
6700B Rockledge Drive, Suite 2500, MSC 6910
Bethesda, MD 20892

RE: Final Report of Reportable Situation (SFNS0521)

Dear Dr. Morse,

The University of Maryland Baltimore (UMB), in accordance with Assurance No. D16-00125 (A3200-01) and PHS Policy IV.F.3., provides this final report on a reportable situation involving non-compliance with IACUC approved satellite housing husbandry standard operating procedures (SOP). This incident was first reported to OLAW Division of Compliance Oversight on June 1, 2021 by the OAWA Director.

BACKGROUND

On May 25, 2021, the Principal Investigator (PI) responsible for an IACUC approved PI-managed Satellite Facility informed the OAWA of an incident involving an HR personnel matter that upon investigation identified numerous instances of falsified documentation related to animal care (husbandry tasks marked as completed; yet staff member was not on campus). Upon consultation with NIH OLAW, UMB was informed that while there were no animal welfare concerns identified, this incident is reportable due to noncompliance with IACUC approved Satellite Facility SOPs.

ACTIONS TAKEN, COMMITTEE DELIBERATIONS AND OUTCOME

The IACUC Chair was informed of the incident on May 25th, reviewed the PI's notification and requested additional preliminary information prior to IACUC review related to how far back badge entry records were reviewed to determine whether the identified deficiencies were ongoing or recent events; were there any days identified that the caretaker did not enter the room at all (AM and PM health checks not performed); has the lab experienced any unexpected outcomes during this timeframe that may have resulted due to lack of health checks; and clarification if there has been any issues with performing health checks since this event.

The IACUC met on June 21, 2021 and reviewed the PI's notification report, the IACUC Chair's request for additional information, and the PI's response. The committee determined that the PI's response was timely, thorough, and satisfactory. While there was non-compliance with the approved facility SOPs; there were no animal welfare concerns identified.

The following corrective actions were taken:

- The incident occurred on May 21st. The lab manager completed health checks and cage changes on May 22nd. The incident was immediately addressed with the employee and disciplinary action was taken by UMB HR (three-day suspension without pay). Animal health checks were conducted by other trained lab members during this timeframe.
- Upon return to work on May 28th, the caretaker's performance was monitored by 1) weekly review of card (badge) reader records provided by campus police, 2) weekly review of the animal welfare checklists and times/dates of signature, 3) spot checks of cage condition, cage changing and density, 4) continue bi-weekly review of genotyping results and colony management and if necessary, 5) review of video data from the hallways and in the satellite facility.
- Review of badge entry data and records revealed a potential ongoing concern with falsification of husbandry records; however, it was noted that lab staff could enter the satellite facility by key vs. badge entry thereby the data was not 100% reliable. There were three days identified for which twice daily room checks may not have been completed. There were no unexpected outcomes during this timeframe, likely attributable to lab staff's monitoring of colony and ability to identify and resolve any husbandry needs.
- The PI reported one incident since May 28th occurring on June 14th that resulted in the AM health check not being performed or documented. The caretaker was immediately removed from all aspects of animal care. These duties were fulfilled by the lab manager or delegated to other trained lab members.

A Veterinary Resources (VR) Veterinarian reported that since approval of this PI-managed satellite facility, VR has site visited this location three times a week, then once a week and is now currently site visiting once a month. VR has not identified any animal welfare concerns during their visits. The committee determined that the corrective actions taken to ensure animal health and welfare were appropriate, no further information or corrective actions were warranted and this incident could be closed as the individual is no longer involved in animal care and the lab has established appropriate QA/QC procedures to ensure animal welfare.

In relation to this matter, several members raised concerns with HR policies precluding immediate termination for certain grievances. The IACUC Chair informed the committee that the IO is aware of these concerns and is working with Campus HR to review all policies and procedures to address this matter.

While this protocol is supported by PHS funds (NINR Intramural Research Program contract and 5R01NR013601), the IACUC concurred that these findings did not violate the terms and conditions of the grant and did not warrant notification of the Institute/Center.

The UMB is committed to protecting the welfare of animals used in research and appreciates the guidance and assistance provided by OLAW in this regard. Should you have any questions regarding this report, please do not hesitate to contact my office or the (b) (6)

Thank you for your consideration of this matter.

Sincerely,

 (b) (6)

Susan C. Buskirk, DM, MS, CCEP
Vice President
Chief Accountability Officer
Institutional Official for Animal Research
University of Maryland, Baltimore

SCB:ap

cc: IACUC File

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Tuesday, October 12, 2021 4:55 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: UMB # D16-00125 (A3200-01): Final Report

Thank you for this report, (b) (6) We will send a response soon.

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

From: (b) (6)
Sent: Monday, October 11, 2021 9:47 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Buskirk, Susan <sbuskirk@umaryland.edu>; (b) (6)
Subject: UMB # D16-00125 (A3200-01): Final Report
Importance: High

Dear OLAW Division of Compliance Oversight,

Please find attached a PDF copy of the final report signed by our Institutional Official for incident SFNS0521 (*initially reported via phone on 06/01/21*).

If you have any questions or require any additional information, please do not hesitate to contact me directly.
Sincerely,

(b) (6)





Initial Report of Noncompliance

By: J Tubbs

Date: **06-01/2020**

Time: 2:47pm

Name of Person reporting: [redacted] (b) (6)

Telephone #: [redacted] (b) (6)

Fax #:

Email: [redacted] (b) (6)

Name of Institution: University of Maryland Baltimore
Assurance number: D16-00125

Did incident involve PHS funded activity? Y
Funding component: unknown currently
Was funding component contacted (if necessary): _____

What happened?
Individual discovered to be falsifying afternoon health checks from review of access records.

Species involved: mice
Personnel involved:
Dates and times:
Animal deaths: no

Projected plan and schedule for correction/prevention (if known): _____

Unknown at this time

Projected submission to OLAW of final report from Institutional Official:

60-90d
OFFICE USE ONLY
Case # _____