



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

May 5, 2021

Re: Animal Welfare Assurance
A3255-01 [OLAW Case 2M]

Dr. Christopher S. Brown
Institutional Official
Vice President for Research
University of Alabama- Birmingham
1720 2nd Ave. S, (b) (4)
Birmingham, AL 35294-0107

Dear Dr. Brown,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your April 19, 2021 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of Alabama at Birmingham, following up on an initial telephone report on April 29, 2021. According to the information provided, OLAW understands that 62 mice had been housed for up to three weeks in a laboratory that had not been approved as a satellite facility. Although the animals were not routinely checked on weekends, no health problems were noted.

The corrective actions consisted of counseling the Principal Investigator and staff on adhering to the protocol and institutional policies. The Institutional Animal Care and Use Committee (IACUC) required additional documentation and oversight and will review a request for satellite housing.

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.

Sincerely,

(b) (6)

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

cc: IACUC Chair

April 19, 2021

Brent Morse, D.V.M.
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
6705 Rockledge Drive
RKL1, Suite 360, MSC 7982
Bethesda, Maryland 20892-7982
Assurance # A3255-01

Dear Dr. Morse:

Below is the description of 2 unapproved deviations from the Guide for the Care and Use of Laboratory Animals and/or the PHS Policy. Both instances were discovered during the most recent AAALAC site visit and follow-up for the Post-Site Visit Communication. The deviations involved use of an unapproved non-pharmaceutical grade drug, and unapproved housing of rodents outside of designated animal facilities. The site visit occurred 3/22-26 with post-site visit follow-up occurring over the last few weeks. Additional individual details and the described corrective actions for each incident are included below.

On March 24, 2021, nonpharmaceutical grade meloxicam was found during the site visit to a laboratory. The nonpharmaceutical grade drug had only recently been purchased (<1 month) and less than 10 mice had been administered the drug. Corrective actions included discontinuation of its use along with no surgeries performed until the pharmaceutical grade version was obtained. The vet staff and IACUC Associate Director provided education to the PI at the time of discovery and as a follow-up to the lab visit. No animal health issues were present or discovered during the time period of administration. The project is federally funded through award # R01MH113645.

- * On March 23, 2021, during the site visit to a laboratory approved to house mice up to 6 days outside of program controlled facilities, it was determined that some animals were being housed up to 3 weeks. This deviation involved approximately 62 mice over the course of a year. Corrective actions include written communication from the PI about how the deviation occurred and what steps the lab would take to ensure it did not recur. Additional documentation and oversight have been required. The Post Approval Monitor and IACUC Chair provided education on the importance of following the approved protocol, and the PI will review the approved housing requirements with all staff. No animal health issues were found during the audit and no clinical health cases were documented. All cages were well-maintained and clean, and properly supplied with food and water. The IACUC is currently reviewing a request to continue this housing in the future. The project is federally funded through award # R56NS103089.

All sites will be inspected by the IACUC during the next semi-annual inspection to ensure corrective actions are still in place.

If you require additional information or clarification, please do not hesitate to let me know.

Sincerely,

(b) (6)

Christopher S. Brown, Ph.D.
Institutional Official and Vice President for Research

cc:

(b) (6)

Robert A. Kesterson, Ph.D., IACUC Chair
Amanda Watts, M.S., C.P.I.A., IACUC Director

(b) (6)

AAALAC International

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, May 5, 2021 7:11 AM
To: Watts, Amanda
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Final Noncompliance Report

Thank you for these reports, Ms. Watts. We will send responses soon.

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

From: Watts, Amanda <wattsaj@uab.edu>
Sent: Monday, May 3, 2021 12:45 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: Final Noncompliance Report

Please find attached a final report for 2 items originally included in a preliminary report to Dr. Wolfe on 4/29/21. One additional item related to the preliminary report will be included in a future mailing.
Please let me know if you need additional information.
Thank you,

Amanda Watts, MS, CPIA | Director
Institutional Animal Care and Use Committee
UAB | The University of Alabama at Birmingham
CH19 403M | 1720 2nd Ave S | Birmingham, AL 35294-2041
P: (b) (6) | wattsaj@uab.edu

**Let's do this.
Together.**
#UABUNITED





Initial Report of Noncompliance

By:

(b) (6)

Date: 4/29/21

Time: 11:45

Name of Person reporting: AMANDA WATTS

Telephone #: (b) (6)

Fax #:

Email:

Name of Institution: Univ Alabama - BirminghamAssurance number: A3255Did incident involve PHS funded activity? YES

Funding component: _____

Was funding component contacted (if necessary): _____

What happened?

Mice housed outside vivarium longer than approved.
Mice not checked on weekends.

Species involved: Mice

Personnel involved:

Dates and times:

Animal deaths:

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

Counsel PI. Increase PAM

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY

Case # _____