



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

January 24, 2022

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

Dr. Christopher S. Brown
Institutional Official
Vice President for Research
University of Alabama- Birmingham
1720 2nd Ave. S, 720C
Birmingham, AL 35294-0107

Dear Dr. Brown,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your January 18, 2022 letter reporting several instances 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 October 13, 2021. According to the information provided, OLAW understands the following about the incidents and the corresponding corrective actions:

- 1) Animal activities had been performed by personnel not listed on the approved protocol, although the individuals had been appropriately trained and were enrolled in the occupational health and safety program. No adverse actions occurred with the mice involved.

Corrective action: All individuals performing animal activities have been added to the correct protocol and have been counseled to check the protocol prior to beginning animal work.

- 2) The protocol did not include an unexpected phenotype which resulted in mice with skin irritations.

Corrective action: The veterinary staff was consulted and the skin irritations were treated, the protocol was amended, and the Principal Investigator was retrained on monitoring and on reporting unexpected outcomes. Observations and treatments are now being documented and the laboratory was placed under enhanced post-approval monitoring (PAM).

- 3) A harem breeding scheme had been used that was not described in the protocol.

Corrective action: The PI and staff were retrained and the laboratory was placed under enhanced PAM. The PI developed a corrective/preventive action plan incorporating all of the aforementioned items.

Based on its assessment of this explanation, OLAW understands that measures have been implemented for each of the noncompliant items to correct and prevent recurrence of these problems. OLAW concurs with the actions taken by the institution to comply with the PHS Policy.

Page 2 – Dr. Brown
January 24, 2022
OLAW Case A3255-2S

Sincerely,

(b) (6)

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

cc: IACUC Chair



THE UNIVERSITY OF ALABAMA AT BIRMINGHAM

Institutional Animal Care and Use Committee (IACUC)

January 18, 2022

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 unapproved deviations from the Guide for the Care and Use of Laboratory Animals and/or the PHS Policy identified and included in a preliminary report to OLAW on October 13, 2021. The incidents of non-compliance were identified through an anonymous report involving one laboratory. The corrective action for each incident is also described.

Deviation from approved protocol:

- (1) The investigator allowed personnel not listed on the approved protocol to manage mice and perform procedures. All personnel were listed on at least one protocol for the investigator and had completed all of the required training and health enrollment, but were at times working under protocols to which they had not been added. It is unclear the exact number of animals this incident involved, but the average census during this 3 month time period was approximately 300 cages. No adverse outcomes were documented for animals during this period. Action: All individuals have been included on the appropriate protocols and have been trained to check protocols before beginning work with animals.
- (2) The investigator failed to update the approved protocol for an unexpected phenotype. While animals were being appropriately monitored and treated for the unexpected skin irritations in consultation with the veterinary staff, this unexpected outcome was not documented in the protocol. The unexpected phenotype was observed in approximately 30 mice over the 3 month period for this study. Action: The protocol has been amended. The PI has undergone remedial training for monitoring and reporting unexpected outcomes and is required to maintain observation and treatment documentation. Additional IACUC oversight has been implemented and will continue to occur with our post-approval monitoring (PAM) staff over the next 6 months.
- (3) The investigator was using a harem breeding scheme that had not been described in the approved protocol. This noncompliance affected approximately 75 cages of mice and no adverse outcomes were documented. Action: The investigator and staff were required to complete remedial training for breeding and colony management and are receiving enhanced oversight by our PAM staff for the next 6 months.

Institutional Animal Care and Use Committee
403 Community Health
933 19th St S
205.934.7692
FAX 205.934.1188

Mailing Address:
403 CH19
1530 3RD AVE S
BIRMINGHAM AL 35294-2041



THE UNIVERSITY OF ALABAMA AT BIRMINGHAM

Institutional Animal Care and Use Committee (IACUC)

In addition to the above-described corrective actions, the investigator was also required to provide a written plan documenting the changes already implemented and actions the lab would take to ensure these issues do not recur. The investigator's Director and Chair were also included in the corrective action plan. These incidents involved work funded by NIH award R01HL136165.

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

(b) (6)

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Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, January 19, 2022 7:39 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Noncompliance final report (A3255-01)

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: Tuesday, January 18, 2022 3:39 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: [EXTERNAL] Noncompliance final report (A3255-01)

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 find attached the final report for noncompliance incidents included in a preliminary report on October 13, 2021.
Please let me know if you have further questions.
Thank you,

(b) (6)



Initial Report of Noncompliance

By: (b) (6)

Date: 10/13/21

Time: 10:00

Name of Person reporting: (b) (6)

Telephone #: (b) (6)

Fax #:

Email:

Name of Institution: U of Alabama

Assurance number: A3255

Did incident involve PHS funded activity? Yes

Funding component:

Was funding component contacted (if necessary):

What happened?

deviation from protocol - barren breeding instead of trio breeding. Personnel not listed on protocol

Species involved: mice

Personnel involved:

Dates and times:

Animal deaths: no

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

Retraining, go back to trio breeding, enhanced PAM

Projected submission to OLAW of final report from Institutional Official:

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Case #