



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

June 25, 2021

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

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 June 21, 2021 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 April 29, 2021. According to the information provided, OLAW understands the following about the incidents and the corresponding corrective actions:

- 1) Forty mice were subjected to toe clipping although this procedure had not been described in the approved protocol. The procedure had been performed in accordance with institutional policy.

Corrective action: The protocol was amended to include the procedure and the investigator was counseled to read and follow the protocol.

- 2) Two mice failed to receive the full post-operative analgesic regimen described in the protocol.

Corrective action: Surgeries were stopped until appropriate analgesia was obtained, the protocol was amended to include an alternative analgesic regimen, the Principal Investigator was counseled to follow the protocol, and the laboratory was placed under enhanced post-approval monitoring.

- 3) Expired euthanasia solution was used on 1800 mice. The required secondary physical method of euthanasia was successfully used to ensure death.

Corrective action: A different euthanasia method will be used until a new stock of euthanasia solution is acquired. The investigator submitted a plan of prevention.

- 4) Two mice were given expired carprofen. No adverse effects were reported due to use of the expired agent.

Corrective action: Further surgeries were stopped until in-date drugs were acquired. The investigator was counseled not to use expired agents.

- 5) Eight mice were euthanized with expired isoflurane. The required secondary physical method of euthanasia was successfully used to ensure death.

Corrective action: New isoflurane was obtained and the investigator was counseled not to use expired agents.

Based on its assessment of these explanations, OLAW understands that measures have been implemented in each situation to correct and prevent recurrence of the problem. While OLAW concurs with the actions taken by the institution to comply with the PHS Policy, we note that repeated instances of the same noncompliance, such as use of expired drugs, may require program wide solutions. Other institutions faced with this challenge have implemented use of color coded expiration stickers, have assigned individuals in laboratories to check expiration dates, and have applied sanctions to laboratories with repeat deficiencies. Thank you for keeping OLAW apprised on this matter.

Sincerely,

(b) (6)

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

cc: IACUC Chair

UAB THE UNIVERSITY OF ALABAMA AT BIRMINGHAM
Institutional Animal Care and Use Committee (IACUC)

June 21, 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 unapproved deviations from the Guide for the Care and Use of Laboratory Animals and/or the PHS Policy identified and discussed at the May 26 (2021) IACUC full committee meeting. The incidents of non-compliance were identified through post approval monitoring. Described corrective action for each incident is also included.

Deviation from approved protocol: An investigator was performing unapproved toe clips in mice. Approximately 40 mice were involved. Toe clips were performed in accordance with university policy and AAALAC guidelines for age and methods, but the investigator had failed to add the procedure to their new protocol prior to performance. The investigator stopped performance of tail clips, and submitted a modification, which was approved. The investigator was also reminded of the importance of checking their protocol before doing a procedure by both the Compliance Coordinator and the IACUC Chair. This incident involved work funded by NIH award R01HL138470.

Deviation from approved protocol: An investigator failed to provide the full regimen of analgesia approved in the protocol. Two mice received the required NSAID, but not an opioid analgesic following surgery. The investigator stopped all surgeries until the appropriate analgesia was obtained. The protocol has been modified and approved to include an alternative analgesic regimen. The PI was reminded of the importance of reviewing their protocol prior to beginning a procedure. The Compliance Coordinator continues to monitor the analgesia records of the lab to ensure continued compliance with the modified protocol. This incident did not involve PHS funds.

Use of expired substances: This incident involved the use of expired euthanasia solution in approximately 1800 mice. A secondary, physical method of euthanasia was performed according to university policy. The investigator was required to immediately switch euthanasia methods until new solution was procured and was required to provide a plan to prevent recurrence. This incident involved work funded by NIH award R01HL149159.

Use of expired substances: This incident involved the administration of expired carprofen to 2 mice. There were no animal health issues reported for these animals. The investigator stopped all surgical procedures until new carprofen was obtained. The investigator was reminded of the importance of checking expiration dates for all substances prior to administration. This incident did not involve PHS funds.

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

**UAB THE UNIVERSITY OF
ALABAMA AT BIRMINGHAM**
Institutional Animal Care and Use Committee (IACUC)

Use of expired substances: This incident involved the use of expired isoflurane for euthanasia in 8 mice. A secondary, physical method of euthanasia was performed according to university policy. The investigator immediately obtained new isoflurane and was reminded of the importance of checking expiration dates for all substances prior to use. This incident did not involve PHS funds.

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
Gary L. Borkowski, D.V.M., M.S., Global Director, AAALAC International

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Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, June 25, 2021 7:07 AM
To: Watts, Amanda
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Noncompliance report

Thank you for this report, Ms. Watts. We will send a response soon.

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

From: Watts, Amanda <wattsaj@uab.edu>
Sent: Wednesday, June 23, 2021 12:17 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: (b) (6) Kesterson, Robert Allen <kesterson@uab.edu>
Subject: Noncompliance report

Dear Dr. Morse,
Please find attached a letter describing recent noncompliance incidents investigated by our IACUC. Please let me know if you have any questions.
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: U of Alabama - Birmingham

Assurance number: A3255

Did incident involve PHS funded activity? Yes

Funding component:

Was funding component contacted (if necessary):

What happened?

40 mice were toe clipped but not on protocol,
 Mice < 7 days old, No problems w/ mice

Species involved: Mice

Personnel involved:

Dates and times:

Animal deaths:

Projected plan and schedule for correction/prevention (if known):
 Counsel PE, Enhanced PAM

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY

Case #