



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

February 2, 2022

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

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 25, 2022 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 December 13, 2021. According to the information provided, OLAW understands that on two occasions, expired anesthetic was given to a total of 185 mice. There was no adverse outcome due to using the expired agent.

The corrective actions consisted of stopping the activities until in-date drugs were obtained. The investigator and staff were retrained on checking expiration dates of drugs prior to administration, a drug inventory system will be implemented by the laboratory, and the laboratory will be subject to enhanced post- approval monitoring.

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 institution 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



THE UNIVERSITY OF ALABAMA AT BIRMINGHAM

Institutional Animal Care and Use Committee (IACUC)

January 25, 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 December 13, 2021. The incidents of non-compliance were identified through post-approval laboratory audits. The corrective action for each incident is also described.

Use of expired materials

There were two instances where labs were using expired Xylazine for anesthesia. In both cases the expired substance was used in combination with another anesthetic, and there were no adverse outcomes from the anesthetic events. The first event included approximately 125 mice and involved work funded by NIH award R01EY029341. The second event included approximately 60 mice and involved work funded by NIH award R01AR072213. In both cases procedures were halted until new drugs were obtained, and the investigator and staff were retrained to check expiration dates before beginning procedures. Research staff were also encouraged to implement an inventory system to identify expiring materials. These labs will receive additional oversight for the next 6 months.

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)

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

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, February 2, 2022 7:41 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Noncompliance Report- A3255-01

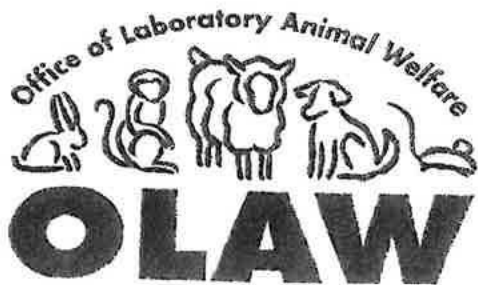
Thank you for this report, (b) (6) We will respond soon.
Axel Wolff

From: (b) (6)
Sent: Tuesday, February 1, 2022 9:57 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: [EXTERNAL] Noncompliance 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 a final report for noncompliance. Please let me know if you have any questions.
Thank you,

(b) (6)



Initial Report of Noncompliance

By: (b) (6)

Date: 12/13/21

Time: 10:00

Name of Person reporting: (b) (6)

Telephone #: (b) (6)

Fax #:

Email:

Name of Institution: U of Alabama - Birmingham

Assurance number: A 3255

Did incident involve PHS funded activity? Yes

Funding component: _____

Was funding component contacted (if necessary): _____

What happened?

Expired xylazine given to mice / Mice kept in lab overnight although not approved. No problems w/ animals.

Species involved: Mice

Personnel involved:

Dates and times:

Animal deaths:

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

Counsel PI

Projected submission to OLAW of final report from Institutional Official:

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Case # _____