



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

March 21, 2022

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

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 February 24, 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 December 13, 2021, telephone notification. According to the information provided, OLAW understands that a lab member failed to administer the full analgesic regimen to one hundred and forty-two mice, as approved in the protocol. The lab member administered an NSAID exclusively, instead of the IACUC approved opioid/NSAID combination. There were no animal welfare issues as a result of the PHS-funded noncompliance, which was identified during a post-approval audit.

The corrective actions consisted of the investigator immediately discontinuing surgical procedures, and in consultation with the veterinarian, submitted a protocol amendment. Lab personnel were retrained on the significance of reviewing the approved protocol prior to the initiation of studies and enhanced oversight of surgical procedures performed by the lab will be conducted for the ensuing 6 months.

Based on the information provided, OLAW is satisfied that appropriate actions have been taken to investigate, correct and prevent recurrence of the noncompliance. We appreciate having been informed about this matter and find no cause for further action by this Office.

Sincerely,

Neera V. Gopee -S

Digitally signed by Neera V.
Gopee -S
Date: 2022.03.21 13:27:02 -04'00'

Neera V. Gopee, DVM, PhD, DACLAM, DABT
Associate Director, Animal Welfare Policy
Office of Laboratory Animal Welfare
National Institutes of Health

cc: IACUC Chair

February 24, 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 incident of non-compliance was identified through post-approval laboratory audits. The corrective action is also described.

Deviation from approved protocol

One instance of deviating from the approved analgesia regimen was noted during a routine audit. The lab member had failed to administer the approved opioid portion of the analgesia, but did provide the approved NSAID. There were no adverse outcomes noted for these animals. This incident involved 142 mice and work funded by NIH award R01NS112203. The investigator discontinued surgical procedures to submit a modification with veterinary consultation. The lab received retraining on the importance of reviewing the approved protocol before beginning studies. This lab will receive additional oversight for surgical procedures 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, March 16, 2022 7:24 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: final reports

Thank you for these reports, (b) (6) We will send replies soon.
Axel Wolff

From: (b) (6)
Sent: Tuesday, March 15, 2022 9:27 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: [EXTERNAL] final reports

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.

Good morning,
Please find attached the final reports to for 2 incidents already filed as preliminary reports. 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: A3255

Did incident involve PHS funded activity? Yes

Funding component: _____

Was funding component contacted (if necessary): _____

What happened?

Mice not receiving full analgesic regimen for intracranial injections. No problems noted.

Species involved: *Mice*

Personnel involved:

Dates and times:

Animal deaths:

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

Amend protocol, enhanced oversight.

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY

Case # _____