



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) 402-7065

July 2, 2019

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

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 letter dated June 17, 2019 regarding a reportable incident at your institution. This is a final report that was preceded by a preliminary report to this office on April 11, 2019.

According to the information provided, our office understands that on a post approval monitoring visit, it was determined that 202 mice that had undergone intracranial surgeries were not provided analgesics as required on the protocol that was approved by the Institutional Animal Care and Use Committee (IACUC). The activity was not PHS funded.

The IACUC held convened meetings to address the issue on March 27 and May 29, 2019. Due to a history of repeated similar noncompliances at the laboratory, the quorum voted to suspend all the Principal Investigator's animal activities for one year, to enhance post approval monitoring after the suspension, and to retrain two of the staff members involved in the incident.

Based on its assessment of this explanation, OLAW understands that measures have been taken to prevent recurrence of this problem. OLAW concurs with the actions taken by your institution to comply with the PHS Policy on Humane Care and Use of Laboratory Animals. Although this activity was not PHS funded, the establishment and application of policies and practices that are consistent with the provisions of the PHS Policy on Humane Care and Use of Laboratory Animals are commendable and avoid the perception of a double standard. Please note that reports of noncompliance to OLAW should include dates of occurrence when describing the incident. Please include this information in future submissions.

Sincerely,

(b) (6)

Nicolette Petervary, VMD, DACAW
Veterinary Medical Officer
Office of Laboratory Animal Welfare



THE UNIVERSITY OF ALABAMA AT BIRMINGHAM

Institutional Animal Care and Use Committee (IACUC)

June 17, 2019

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:

This is a final report describing a deviation from PHS policy and the actions taken by the University of Alabama at Birmingham (UAB) Institutional Animal Care and Use Committee following the preliminary report we made to your office.

Failure to follow the approved Institutional Animal Care and Use Committee (IACUC) protocol: During a laboratory audit conducted by the IACUC Compliance Coordinator, it was discovered that 202 intracranial surgical procedures in mice were conducted without providing analgesic as described in the approved IACUC protocol. The University of Alabama at Birmingham IACUC met on Wednesday March 27 and May 29, 2019, and discussed the noncompliance associated with investigator's staff performing intracranial procedures without administration of analgesics per the approved protocols. The quorum decision of voting members and corrective actions are as follows:

For the principal investigator:

1. Immediate suspension of all animal research activities for a period of one year. No procedures of any kind with live animals can be conducted during this suspension. Staff members may not perform any procedures with live animals during this suspension under the direction or oversight of the investigator.
2. Increased laboratory audits conducted by the IACUC for a period of one year from the date of reinstatement from suspension. These audits may be unannounced, and PI and staff must fully comply with the audit request.
3. Management and/or disposition of the PI's mouse colony during suspension is to be determined based on the outcome of discussions with the PI's primary department chair, Animal Resources Program (ARP), and IACUC. (Note that the PI and department chair have preliminarily requested to transfer most all animals to other investigators.)
4. A plan for reinstatement and oversight is to be developed in the next six months based on the outcome of discussions with the primary department chair, ARP, and IACUC. The full IACUC committee must approve the final plan before the PI's reinstatement to use animals at UAB will be approved.

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

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THE UNIVERSITY OF ALABAMA AT BIRMINGHAM

Institutional Animal Care and Use Committee (IACUC)

For the two staff members:

1. Retraining via online course work and testing.
 - a. Working with the IACUC
 - b. Pain Management in Laboratory Animals
2. Meet with IACUC Director to discuss knowledge of protocols on which they are listed as active personnel.
 - a. How to access and use the institutions protocol online system.
 - b. Review of protocol components to determine what procedures the IACUC has approved.
3. Meet with IACUC Director and/or Chair to discuss the importance of communication between the PI and staff, and all responsibilities when working with animals.

The non-compliance procedures did not involve PHS funds but were supported via funds from an internal startup package and the Department of Defense. OLAW will be updated once the reinstatement and oversight plan has been approved by the UAB IACUC.

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: Samuel C. Cartner, D.V.M., Ph.D., ARP Director
Robert A. Kesterson, Ph.D., IACUC Chair
(b) (6)
David Cannon, B.A., C.P.I.A., IACUC Director
Gary L. Borkowski, D.V.M., M.S, Global Director, AAALAC International
(b) (6)
USAMRMC Office of Research Protections (ORP)

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Retrieved from Animal Research Laboratory Overview (ARLO)

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, June 24, 2019 11:55 AM
To: Cannon, David Grove; OLAW Division of Compliance Oversight (NIH/OD)
Cc: Cartner, Samuel Corbin; Kesterson, Robert Allen; (b) (6)
Subject: RE: OLAW A3255-01 noncompliance report Mar 2019.pdf

Thank you for this final report Mr. Cannon. We will send an official response soon.

Best regards, Brent Morse

Brent C. Morse, DVM, DACLAM
Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health

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From: Cannon, David Grove [mailto:dgcannon@uab.edu]
Sent: Monday, June 24, 2019 10:58 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: 'accredit@aaalac.org' <accredit@aaalac.org>; Cartner, Samuel Corbin <scartner@uab.edu>; Kesterson, Robert Allen <kesterso@uab.edu>; (b) (6)
Subject: RE: OLAW A3255-01 noncompliance report Mar 2019.pdf

Dear Dr. Morse,

Attached is Final incident report for Assurance A3255-01 sent on behalf of Christopher S. Brown, UAB's Institutional Official. Please let me know if you have any questions that I can answer or provide additional clarity.

Sincerely,

David

David Cannon, CPIA | Director IACUC
Institutional Animal Care and Use Committee
UAB | The University of Alabama at Birmingham
CH19 403G | 933 19th St. South | Birmingham, AL 35294-2041
P: (b) (6) | dgcannon@uab.edu



Celebrate our 50th anniversary with us!



Initial Report of Noncompliance

By: *[Signature]*

Date: *4/11/19*

Time: *Voicemail*

Name of Person reporting: *David Cannon*

Telephone #: *(b) (6)*

Fax #:

Email:

Name of Institution:

Univ of Alabama at Birmingham

Assurance number:

A3255

Did incident involve PHS funded activity? _____

Funding component: _____

Was funding component contacted (if necessary): _____

What happened? *Analgesic not provided as required by protocol. Continuing noncompliance from previous event with same researcher.*

Species involved:

Personnel involved: *Researcher*

Dates and times:

Animal deaths:

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

IACUC to meet w/ researcher + Dept. Chair and recommend one year suspension of researcher

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY

Case # _____