



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 22, 2019

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

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 July 5, 2019 letter reporting two instances of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of Alabama at Birmingham. According to the information provided, OLAW understands the following about the incidents and the corresponding corrective actions:

- 1) Approximately 100 mice failed to receive the full analgesic regimen following surgery. Specifically, only one of two analgesics had been given. No adverse effects were reported with the mice due to this action.

Corrective action: The surgeries were stopped until all analgesics were obtained. The Principal Investigator (PI) and staff were retrained on rodent surgery and counseled on following the protocol.

- 2) A non-pharmaceutical grade analgesic was used on 140 mice and the records were incomplete.

Corrective actions: The PI was counseled to use pharmaceutical grade agents and to maintain accurate surgical logs including administration of all drugs. The PI and staff were retrained on rodent surgery.

Based on its assessment of these explanations, OLAW understands that measures have been implemented in each situation to prevent recurrence of the 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 Contact
IACUC Director



Institutional Animal Care and Use Committee (IACUC)

July 5, 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:

Below are descriptions of unapproved deviations from the Guide for the Care and Use of Laboratory Animals and/or the PHS Policy identified and discussed during the June 26 (2019) IACUC full committee meeting. Both incidents of non-compliance were discovered through post approval monitoring and each of the three reports involved a different investigator. Described corrective actions for each incident are also included.

Failure to follow the IACUC approved protocol: A routine laboratory audit conducted by the Compliance Coordinator determined that approximately 100 mice had undergone a surgical procedure without providing the full analgesic regimen. Animals were to receive a combination of Carprofen and Buprenorphine for intraoperative and postoperative pain management; however, the audit discovered that only Carprofen was provided instead of following the regimen approved in the protocol. No adverse effects were noted in the animals' health status records, and all surgical procedures were halted until the correct analgesics were acquired. Corrective actions: The laboratory staff (including the PI) are required to retake rodent surgery training, and counseling by the Compliance Coordinator on the importance of knowing and following the approved protocol. This incident-involved work funded by NIH grant 1R01EY028037.

Use of unapproved non-pharmaceutical grade analgesic: During a procedural audit, the Compliance Coordinator discovered a laboratory providing a non-pharmaceutical grade analgesic to 140 mice without clarifying this in their approved protocol. The laboratory administration records were also lacking in terms of documenting the administration of this analgesic. Corrective actions: The Compliance Coordinator counseled the PI and staff that pharmaceutical grade analgesics must be used if available, and reinforced the need to maintain accurate surgical logs showing the administration of all drugs. Additionally, all staff, including the PI, must retake rodent surgery training. This incident-involved work funded by NIH grant R01CA183991

Institutional Animal Care and Use Committee
403 Community Health
933 19th St S
205.934.7692
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THE UNIVERSITY OF ALABAMA AT BIRMINGHAM

Institutional Animal Care and Use Committee (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
David Cannon, B.A., C.P.I.A., IACUC Director
Gary L. Borkowski, D.V.M., M.S., Global Director, AAALAC International

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Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Thursday, July 11, 2019 2:20 PM
To: Cannon, David Grove; OLAW Division of Compliance Oversight (NIH/OD)
Cc: Cartner, (b) (6); Kesterson, Robert Allen; (b) (6)
Subject: RE: OLAW A3255-01 noncompliance report June 2019.pdf

Thank you for providing this report. 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

Please note that this message and any of its attachments are intended for the named recipient(s) only and may contain confidential, protected or privileged information that should not be distributed to unauthorized individuals. If you have received this message in error, please contact the sender.

From: Cannon, David Grove [mailto:dgcannon@uab.edu]
Sent: Thursday, July 11, 2019 1:44 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: 'accredit@aaalac.org' <accredit@aaalac.org>; Cartner, (b) (6); Kesterson, Robert Allen <kesterson@uab.edu>; (b) (6)
Subject: OLAW A3255-01 noncompliance report June 2019.pdf

Dear Dr. Morse,

Attached is the UAB IACUCs June noncompliance Final incident report for Assurance A3255-01 sent on behalf of Christopher S. Brown, UAB's Institutional Official. These are two UAB PIs that had compliance issues. 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
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