



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

March 12, 2019

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

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 March 4, 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) Two pigs were singly housed during acclimation and fed an experimental diet not described in the approved protocol. There was no adverse impact on the animals.

Corrective action: The investigator was counseled and the protocol was amended to include the diet and acclimation deviation.

- 2) Eighty five mice were given an analgesic cocktail following surgery and one of the drugs in the mixture had expired. There was no adverse impact on the animals.

Corrective action: The surgeries were stopped until in-date analgesics were obtained and the investigator was counseled on observing expiration dates of all drugs given to animals.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to correct and prevent recurrence of these problems. 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
Robert Gibbens, D.V.M., USDA-APHIS-AC



THE UNIVERSITY OF ALABAMA AT BIRMINGHAM

Institutional Animal Care and Use Committee (IACUC)

A3255-3A

March 4, 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 February (2019) IACUC full committee meeting. All incidents of non-compliance were discovered through post approval monitoring and involved a single investigator. Described corrective actions for each incident are also included.

Failure to follow the IACUC approved protocol: two swine were singly housed during the acclimation period and provided a special diet containing Cyclosporine that was not included in the approved IACUC protocol. The special diet had been included in a previous version of the PI's protocol, but was not included in the current version. There were no adverse effects to the animals noted due to the deviations. This incident-involved work funded by NIH grant R01HL114120.

Expired compound administered to rodents: A routine laboratory audit conducted by the Compliance Coordinator determined that 85 mice had undergone a surgical procedure using an expired drug. Animals received a combination of Carprofen and Buprenorphine analgesic for postoperative pain management; however, the audit discovered that the Carprofen used was past its expiration date (although the other analgesic was within date and fully effective). No adverse effects were noted in the animals' health status records, and all surgical procedures were halted until the correct analgesics could be acquired. This incident-involved work funded by NIH grant R01HL114120.

Corrective actions included counseling by the Compliance Coordinator on the importance of knowing and following the approved protocol, and protocol modification for special diet and acclimation deviations. Ordering of in-date Carprofen along with counseling by the Compliance Coordinator related to careful observation of expiration dates for any compounds administered to animals was reinforced.

Institutional Animal Care and Use Committee
403 Community Health
933 19th St S
205.934.7692
FAX 205.934.1188

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403 CH19
1530 3RD AVE S
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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
James Swearingen, D.V.M., Global Director, AAALAC International

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Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Thursday, March 7, 2019 1:49 PM
To: Cannon, David Grove
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: OLAW A3255-01 noncompliance report Mar 2019.pdf

Thanks Dave. We'll send a response soon.
Axel Wolff

From: Cannon, David Grove <dgcannon@uab.edu>
Sent: Thursday, March 7, 2019 10:42 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: 'accredit@aaalac.org' {accredit@aaalac.org} <accredit@aaalac.org>; Cartner, Samuel Corbin <scartner@uab.edu>; Kesterson, Robert Allen <kesterso@uab.edu>
Subject: 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
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