



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

May 1, 2019

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

Dr. Christopher S. Brown  
Institutional Official  
Vice President for Research  
University of Alabama- Birmingham  
1720 2<sup>nd</sup> Ave. S, 720C  
Birmingham, AL 35294-0107

Dear Dr. Brown,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your April 15, 2019 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. According to the information provided, OLAW understands that 16 mice underwent an unapproved ligation surgery without prior approval. There were no adverse effects to the animals. The involved animal activity was not funded by the PHS.

It is understood that counseling by the Compliance Coordinator took place on the importance of knowing and following the approved protocols and improved communication in order to prevent a recurrence of the incident. The investigators have implemented a corrective action plan consisting of quarterly review of all protocols and instituted a "Time-Out" policy/form that confirms associated protocols with planned procedures. They have also modified their protocols.

OLAW appreciates the prompt consideration of this matter by the University of Alabama at Birmingham, which was consistent with the philosophy of institutional self-regulation. Based on the information provided, OLAW is satisfied that appropriate actions have been taken to investigate and correct the deficiency, and to prevent recurrence. Although this activity was not PHS funded, the application of the standards of the PHS Policy across the animal care and use program reduces any potential appearance of a double standard. We appreciate being informed of this matter and find no cause for further action by this office.

Sincerely,

(b) (6)

Brent C. Morse, DVM  
Director  
Division of Compliance Oversight  
Office of Laboratory Animal Welfare

cc: IACUC Contact



THE UNIVERSITY OF ALABAMA AT BIRMINGHAM

*Institutional Animal Care and Use Committee (IACUC)*

A3255-2C

April 15, 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 and March (2019) IACUC full committee meeting. This incident of non-compliance was discovered through a PI-to-PI animal transfer request indicating prior procedures performed on the animals. Described corrective actions for the incident is also included.

Performing unapproved procedure without IACUC approval. Mice (16) underwent an unapproved ligation surgery without prior approval. This was a collaboration between two laboratories where each group thought the other had updated their protocol to include the performed procedure. There were no adverse effects to the animals noted due to the deviations. This incident did not involve any federal or external funding source.

Corrective actions included counseling by the Compliance Coordinator on the importance of knowing and following their approved protocols, and improved communication to lessen the chance of future compliance issues. The PIs preemptively provided the following corrective actions that were approved by the IACUC. Immediate modification of protocols, quarterly review of all laboratory protocols performed by each laboratory, instituting a "Time-Out" policy/form that confirms associated protocols with planned procedures.

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 Swearengen, D.V.M., Global Director, AAALAC International

Institutional Animal Care and Use Committee  
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Retrieved from Animal Research Laboratory Overview (ARLO)

**Morse, Brent (NIH/OD) [E]**

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Tuesday, April 23, 2019 7:32 AM  
**To:** Cannon, David Grove; OLAW Division of Compliance Oversight (NIH/OD)  
**Cc:** Cartner, Samuel Corbin; Kesterson, Robert Allen  
**Subject:** RE: OLAW A3255-01 noncompliance report Mar 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

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**From:** Cannon, David Grove [mailto:dgcannon@uab.edu]  
**Sent:** Monday, April 22, 2019 3:19 PM  
**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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Celebrate our 50<sup>th</sup> anniversary with us!