



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 17, 2020

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

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 March 12, 2020 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 (UAB) following up on an initial January 30, 2020 notification by telephone.

According to the information provided, this Office understands that the UAB Animal Care and Use Committee (ACUC) determined that instances of noncompliance occurred with respect to: performance of surgical procedures without IACUC approval and administration of expired compounds to rodents. It is noted the two incidents were discussed during the February (2020) IACUC full committee meeting. The first noncompliance involved a cold exposure behavioral experiment in an undisclosed location overnight without prior approval. The procedure involved 15 mice and occurred on two separate dates. Per the final report, there was no evidence that animal welfare issues based on health status records of the colony beyond the noncompliance itself. The corrective actions included the following:

- A requirement for the PI to provide the UAB IACUC with a written action plan describing how this would be prevented from happening in the future.
- Retraining on use of animals in research for all involved in the incident.
- Unannounced laboratory audits conducted by IACUC office staff.

The second incident was discovered during routine laboratory audit. It was discovered that 35 mice had undergone a surgical procedure where they received a combination of xylazine and ketamine anesthetic. The audit revealed that the xylazine used was past its expiration date. No adverse effects were noted in the animals' health status records (per the final report), and all surgical procedures were halted until in-date analgesics could be acquired. The corrective actions included the following:

- Ordering of in date xylazine before any additional procedures.
- Reinforcement counseling by Compliance Coordinator related to careful observation of expiration dates for compounds administered to animals.

It is noted that these incidents were not associated with PHS funded activities. OLAW assumes the IACUC approved the corrective action measures for both events of noncompliance. Based on its assessment of this explanation, OLAW understands that the University of Alabama at Birmingham has implemented appropriate measures to correct and prevent recurrences of these problems and is now compliant with provisions of the PHS Policy. We appreciate being informed of these matters and find no cause for further action by this Office.

Sincerely,

(b) (6)

Jacquelyn T. Tubbs, DVM  
Veterinary Medical Officer  
Division of Compliance Oversight  
Office of Laboratory Animal Welfare

cc: IACUC Contact

## Wolff, Axel (NIH/OD) [E]

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Monday, March 16, 2020 7:35 AM  
**To:** Cannon, David Grove  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: Final report to OLAW following prelim report

Thanks for this report, Dave. We'll send a response soon.

Axel Wolff

**From:** Cannon, David Grove <dgcannon@uab.edu>  
**Sent:** Friday, March 13, 2020 4:39 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Cc:** Cartner, Samuel Corbin <scartner@uab.edu>; Kesterson, Robert Allen <kesterson@uab.edu>; 'accredit@aaalac.org' <accredit@aaalac.org>  
**Subject:** Final report to OLAW following prelim report

Dr. Morse,

Attached is the UAB IACUCs follow-up noncompliance Final incident report for Assurance A3255-01 sent on behalf of Christopher S. Brown, UAB's Institutional Official. There were two compliance issues discussed at the UAB full committee meeting held in February.

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  
(b) (4) | 933 19th St. South | Birmingham, AL 35294-2041  
P: (b) (6) | [dgcannon@uab.edu](mailto:dgcannon@uab.edu)



Celebrate our 50<sup>th</sup> anniversary with us!

**UAB THE UNIVERSITY OF ALABAMA AT BIRMINGHAM**  
Institutional Animal Care and Use Committee (IACUC)

March 12, 2020

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 final report descriptions of two unapproved deviations from the Guide for the Care and Use of Laboratory Animals and/or the PHS Policy identified and discussed during the February (2020) IACUC full committee meeting. Incidents of non-compliance were discovered through post approval monitoring or confidential reporting to the IACUC. Corrective actions for both incidents are also included.

- Performing procedures without Institutional Animal Care and Use Committee approval: The noncompliance involved performing a cold exposure behavioral experiment in an undisclosed location overnight without prior approval. The procedure involved 15 animals (mice) and occurred on two separate dates. There was no evidence that any animal welfare issues based on health status records of the colony beyond the noncompliance itself. This incident did not involve federal funding.

Corrective actions involved the PI and laboratory staff members. The PI was required to provide the UAB IACUC with a written action plan describing how this would be prevented from happening in the future, retraining on using animals in research was required for all involved, and unannounced laboratory audits will be conducted by the IACUC office staff.

- Expired compound administered to rodents: During a routine laboratory audit, conducted by the Compliance Coordinator, it was discovered that 35 mice had undergone a surgical procedure where they received a combination of Xylazine and Ketamine anesthetic. The audit discovered that the Xylazine used was past its expiration date although the Ketamine 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 did not involve federal funding.

Corrective actions included ordering of in date Xylazine before any additional procedures occur along with reinforcement counseling by the Compliance Coordinator related to careful observation of expiration dates for any compounds being administered to animals.

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

Mailing Address:  
403 CH19  
1530 3RD AVE S  
BIRMINGHAM AL 35294-2041

Obtained by Rise for Animals. Uploaded 08/24/2020

Retrieved from Animal Research Laboratory Overview (ARLO)

**UAB 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

(b) (6)

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## Initial Report of Noncompliance

By: Tubbs

Date: 01/30/2020

Time: 10:04 AM

Name of Person reporting: David Canon

Telephone #: (b) (6)

Fax #:

Email: dgcanon@uab.edu

Name of Institution: Univ. AL @ Birmingham

Assurance number: A3255-01

Did incident involve PHS funded activity? Not sure / No

Funding component: \_\_\_\_\_

Was funding component contacted (if necessary): \_\_\_\_\_

What happened?

Two ppl. in surgical procedures but not on protocol, no animal welfare issues, Prelim. Investigation. IACUC met yesterday

Species involved: Swine

Personnel involved: \_\_\_\_\_

Dates and times: yesterday?

Animal deaths: 0

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

Corrective action pending

Projected submission to OLAW of final report from Institutional Official:

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Case # \_\_\_\_\_