



DEPARTMENT OF HEALTH & HUMAN SERVICES


PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:
Office of Laboratory Animal Welfare
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Home Page: <http://grants.nih.gov/grants/olaw/olaw.htm>

FOR EXPRESS MAIL:
Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive
Bethesda, Maryland 20817
Telephone: (301) 496-7163
Facsimile: (301) 402-7065

March 30, 2017

Re: Animal Welfare Assurance
#A3152-01 (OLAW Case X)

John Mason, Ph.D.
Associate Provost and
Vice President for Research
Auburn University
 Sanford Hall
Auburn University, AL 36849-0001

Dear Dr. Mason,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your March 10, 2017 letter regarding noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Auburn University, which had not been preceded by a preliminary report to OLAW. It was reported that the associated animal activity was not PHS or NSF funded. According to the information supplied, OLAW understands that breeding of mice was conducted on a protocol that expired on August 5, 2016 despite multiple notifications that animal activities were not permitted until a new protocol was approved. An IACUC subcommittee was formed on November 15, 2016 to investigate the continued breeding of these animals. Their findings indicated inaccurate accounting of animal numbers, unnecessary breeding including breeding as a result of failure to wean pups from parent cages, failure to re-derive animals with contagious pathogens, inattention to documentation of animals produced and used on the protocol, and training of graduate students in incorrect methods of colony management. This information was presented by the subcommittee at an IACUC meeting on February 2, 2017.

Corrective actions were decided upon at an IACUC meeting on February 16, 2017 and consisted of the following.

- revocation of the PI's animal use privileges for a minimum of 4 months
- requirement for re-training of the PI and all personnel working under the PI's guidance consisting of online training, hands on mouse training, one-on-one IACUC training for documentation of research activities, and any other training relative to rodent care and use as determined by the attending veterinarian
- requirement for re-derivation of the animals with contagious pathogens to meet the requirements set forth by the Division of Laboratory Animal Health
- if the PI intends to breed animals in the future, a Standard Operating Procedure for breeding colonies must be prepared by the PI and approved by the IACUC
- if the above conditions are met, resumption of animal activity will be considered probationary until the IACUC indicates that it is confident that the PI has the ability to comply with regulations

Page 2 – Dr. Mason
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Based on the information provided, OLAW accepts the corrective actions described to prevent recurrence of the noncompliance. Please contact our office if the corrective actions are not carried out as described. Additionally, please be advised that OLAW recommends prompt preliminary reporting of noncompliance issues with submission of a final report once corrective action has been taken. 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 these matters and find no cause for further action by this Office.

Sincerely,

A handwritten signature in dark ink, appearing to read 'Jane Na', with a stylized flourish at the end.

Jane Na, DVM
Veterinary Medical Officer, OLAW
Office of Laboratory Animal Welfare

cc: IACUC Contact



**Office of Research Compliance
IACUC Administration
115 Ramsay Hall Basement
Auburn University, AL 36849**

**Telephone: 334-844-5978
Fax: 334-844-4391
IACUCadmin@auburn.edu**

March 10, 2017

Dr. Axel Wolff
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
RKL1, Suite 360, MSC 7982
6705 Rockledge Drive
Bethesda, MD 20892-7982

Assurance Number: A3152-01

Dr. Wolff:

This is a report of non-compliance and revocation of animal care and use privileges of a Principal Investigator (PI) at Auburn University. The animal activities at issue were not funded by PHS or NSF, but the activities took place in a facility included in the OLAW assurance referenced above. The PI is not currently funded by NSF. However, an NIH RO1 grant effective January 1, 2017 has been received. The PI has not been authorized by Auburn University to begin work on this project.

Review of the situation:

On August 5, 2016, a mouse research and production protocol expired prior to approval of a new protocol submission. On August 11, the PI was told that all research and breeding activities must cease until a new approved protocol was in place to cover those activities. On October 7, 2016, the IACUC Chair was notified that a litter of mice was found in the colony. Additional litters of mice continued to be found in October and November despite a second reminder to the PI that no research or breeding activities were permitted until a new protocol was in place. In addition, it was found that some of the mice were removed from the colony room with no documentation of their disposition. On November 15, 2016, the IACUC Chair appointed an IACUC subcommittee to investigate continuing breeding of these animals. The subcommittee was provided with current and historical documents related to this situation, and conducted interviews and inquiries as it deemed appropriate to investigate the matter.

Subcommittee Findings:

At the February 2, 2017 IACUC meeting, the subcommittee presented the following findings:

- 1) Inaccurate counting of animals by the PI (counting animals used for research projects, but not those produced and euthanized if they were not the correct genotype),
- 2) Co-housing males and females when breeding was not required or desirable
- 3) Leaving litters in boxes with parents well beyond weaning such that "pups" bred with parents and siblings when breeding was not required or desirable

- 4) Failure to re-derive genotype-specific animals which harbored contagious pathogens
- 5) Inattention to documentation of animals produced and used by the protocol
- 6) Training of graduate students in incorrect methods of colony management

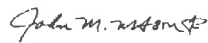
Decisions by the IACUC.

At the IACUC meeting of February 16, 2017 the IACUC:

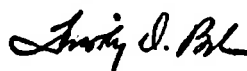
- 1) Revoked privileges of the PI to use animals at Auburn University for a minimum of 4 months.
- 2) Requires re-training of the PI and all personnel working under his guidance to include:
 - a. All online core training required by Auburn University as well as additional training relative to rodent care and use as determined by the University Veterinarian.
 - b. Division of Laboratory Animal Health training on the handling and use of mice (hands on training).
 - c. Additional one-on-one IACUC training related to documentation of research activities.
- 3) Requires re-derivation of their genetically modified animals such that they meet the requirements set forth by the Division of Laboratory Animal Health at Auburn University.
- 4) Requires that if this PI intends to breed animals in the future, a Standard Operating Procedure (SOP) for breeding colonies, separate from research activities, must be prepared by the PI and approved by the IACUC.
- 5) Determined if the PI chooses to meet the above conditions, resumption of the care and use of animals will be considered probationary until the IACUC is confident in the ability of the PI to comply with regulations.
- 6) Noted that documentation of this non-compliance will be held in the IACUC records, communicated to their Department Head, their Associate Dean for Research, their Dean, the Vice President for Research and Economic Development at Auburn University, as well as oversight agencies such as OLAW and AAALAC.

If any additional information is required, please contact the Office of Research Compliance at one.Numb@auburn.edu or IACUCAdmin@auburn.edu.

Sincerely,

 Digitally signed by John M. Mason, Jr.
Date: 2017.03.13 15:41:02 -05'00'

John M. Mason, Jr., Ph.D., P.E.
Auburn University Institutional Official
Vice President for Research and Economic Development



Timothy D. Braden, Ph.D.
Auburn University IACUC Chair
Associate Professor
Anatomy, Physiology & Pharmacology

cc: University Veterinarian – Dr. P. Rynders
Head, Drug Discovery and Development – [ondary Indivi](#)
Associate Dean for Research, Harrison School of Pharmacy – [ondary Indivi](#)
Dean, Harrison School of Pharmacy – [ondary Indivi](#)
Associate Provost & Associate Vice President for Research – [dary Indi](#)
Assistant Vice President for Research Administration – [ondary Indiv](#)
Director, Office of Research Compliance – [condary Individ](#)

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, March 15, 2017 10:42 AM
To: 'IACUC Admin'
Subject: RE: Report of Noncompliance-Auburn University A3152-01

Thank you for this letter, [redacted] We will respond soon.

Axel Wolff, M.S., D.V.M.
 Director, Division of Compliance Oversight
 OLAW

From: IACUC Admin [mailto:OARPROG@auburn.edu]
Sent: Wednesday, March 15, 2017 8:55 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Timothy Braden <bradetd@auburn.edu>; John Mason <jmm0027@auburn.edu>; Pat Rynders <ryndepe@auburn.edu>; [redacted] <[redacted]@auburn.edu>; [redacted] <[redacted]@auburn.edu>; [redacted] <[redacted]@auburn.edu>; [redacted] <[redacted]@auburn.edu>; [redacted] <[redacted]@auburn.edu>; [redacted] <[redacted]@auburn.edu>
Subject: Report of Noncompliance-Auburn University A3152-01
Importance: High

Good Morning, Dr. Wolfe.

Please find attached to this email a report of noncompliance from Auburn University, Assurance Number A3152-01. If you have any questions or need additional information, please let us know.

Thanks,

[redacted]
 Secondary Individual

IACUC Administrator

Office of Research Compliance
 115 Ramsay Hall Basement
 Auburn University, AL 36849

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