



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

April 23, 2019

Re: Animal Welfare Assurance
#A3437-01 (OLAW Case 1D)

Dr. David C. Lee
Vice President for Research
University of Georgia
(b) (4) Paul D. Coverdell Center for
Biomedical and Health Sciences
Athens, GA 30602

Dear Dr. Lee,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your March 29, 2019 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of Georgia. According to the information provided, OLAW understands that neonatal mice were subjected to toe clipping although this activity had not been approved by the Institutional Animal Care and Use Committee (IACUC).

The corrective action consisted of the Institutional Official and IACUC suspending the study. The IACUC required the Principal Investigator (PI) to submit a corrective action plan which included enhanced post approval monitoring (PAM) and having laboratory staff assessed for proficiency by the veterinarians. The IACUC subsequently partially lifted the suspension and required the laboratory staff to undertake retraining and to conduct some animal activities under supervision. The IACUC lifted the suspension fully and required that all staff not yet certified by the veterinarians to be assessed for proficiency, required the submission of weekly PAM reports by the PI, and required unannounced PAM visits. After several months of positive reports, the enhanced oversight was stopped.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to correct and prevent recurrence of this problem. OLAW concurs with the actions taken by the IACUC to comply with the PHS Policy. Please also report the suspension to the NIH funding component. Thank you for informing OLAW about this matter.

Sincerely,

(b) (6)

Axel Wolff, M.S., D.V.M.
Deputy Director
Office of Laboratory Animal Welfare

cc: IACUC Chair



UNIVERSITY OF
GEORGIA

OFFICE OF RESEARCH

147 Paul D. Coverdell Center for Biomedical and Health Sciences
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March 29, 2019

Brent Morse, D.V.M.
Acting Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare (OLAW)
National Institutes of Health
6700B Rockledge Drive, Suite 2500, MSC 6910
Bethesda, MD 20892-6910

RE: University of Georgia, PHS Assurance Number: D16-00276/A3437-01

Dear Dr Morse,

I am writing to provide a final report of a serious deviation from the PHS Policy that was reported to OLAW in a preliminary report on July 12, 2018. Toe clipping of mouse neonates occurred without appropriate IACUC approval.

This work is covered by an IACUC approved protocol and funded by the NIH under grant number R01HL135854.

In July, 2018, the IO initiated a 3-month suspension of new animal experiments, and the IACUC voted to indefinitely suspend any new animal experiments. Aspects of the remedial action plan established to address the issue were completed in August 2018:

- Action 1: Submission of a written compliance plan to be submitted to the IACUC
The plan was submitted, and reviewed and approved at the August 16 IACUC meeting. The plan includes post approval monitoring (PAM) and personnel from the Office of Animal Care and Use and University Research Animal Resources attending lab meetings.
- Action 2: Lab personnel performing procedures to complete ongoing studies must be assessed for competency by URAR veterinarians
This was completed by the first week of August.

At its scheduled meeting on October 18, the IACUC discussed the lab's progress, determined that the ongoing compliance plan was adequate, and voted to initiate a partial lifting of the suspension. The following plan was established:

- Action 1: All lab members must attend in person training on animal research regulations from the Office of Animal Care and Use.
This was completed by the end of October, 2018
- After all lab personnel completed this training, they were allowed to perform the following activities:
 - a. Procedures for maintenance of the breeding colonies: pairing and separating mice, weaning, applying identification, and collecting tissues for genotyping.

- b. Procedures for a single, specified experiment on the protocol, the least invasive of the experiments.
 - c. As the lab started to perform these procedures again, a member of the URAR professional staff was to be present.
- The IACUC would discuss the lab's progress at the next IACUC meeting and consider the appropriateness of allowing any additional experiments

Subsequent to the meeting, the AV informed the IO about the IACUC's October 18 discussions and decisions. He agreed with the IACUC's plan and did not extend his 3-month suspension.

At its scheduled meeting on December 20, 2018, the IACUC reviewed the lab's progress and voted to fully remove any restrictions on the lab's research activities. The IACUC initiated a period of enhanced oversight to assist the lab with transition to full activity. The IACUC required:

- For any person who was not previously been deemed competent at a specific procedure by the lab animal veterinarians, they were to be observed and deemed competent before they were allowed to perform that procedure without animal resources oversight.
- The PI and lab leadership were required to provide post approval monitoring reports to the IACUC once a week until the March IACUC meeting.
- Until the March IACUC meeting, animal resources personnel would make occasional, unannounced observations of lab activities.

The IACUC reviewed the weekly post approval monitoring reports at the regularly scheduled January and February meetings. At its scheduled meeting on March 21, 2019, the IACUC discussed the lab's activities over the past several months, and voted to end the period of enhanced oversight.

The University of Georgia is committed to a high-quality animal care and use program and the welfare of animals used in instruction and research. We take very seriously our institutional responsibility for the evaluation, monitoring, reporting, and correction of our animal care and use program that is the foundation of the PHS Policy. Please contact me if further information or additional corrective actions are needed.

Sincerely,

(b) (6)

David Lee, Ph.D.
Vice President for Research / Institutional Official

Cc:

(b) (6)

Dr. Gaylen Edwards, IACUC Chair, Department Head
Dr. Leanne Alworth, Attending Veterinarian

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, April 10, 2019 8:34 AM
To: Leanne Alworth; OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Final Report -Deviation from PHS Policy

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: Leanne Alworth [mailto:alworth@uga.edu]
Sent: Friday, March 29, 2019 4:09 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: Final Report -Deviation from PHS Policy

Hello Dr Morse,

Attached is a Final report from UGA regarding an event that was first reported July 12, 2018.

Please let me know if you have any questions.

Thank you,

Leanne

Leanne Alworth, MS, DVM, DACLAM
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