



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

September 29, 2021

Re: Animal Welfare Assurance
#A3437-01 (OLAW Case 11)

Dr. Karen Burg
Vice President for Research
University of Georgia
(b) (4) Paul D. Coverdell Center -
500 D.W. Brooks Drive
Athens, GA 30602

Dear Dr. Burg,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your July 28, 2021 final letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of Georgia. A preliminary email report was provided on June 22, 2021. According to the information provided, OLAW understands on June 8, 2021, a researcher collected a volume of blood from mice that was over the approved amount on the protocol and two animals died. The study was PHS funded.

As a corrective measure, the principal investigator (PI) was required to develop and follow a written plan for maintaining compliance and meet with the IACUC to describe how compliance maintained will be accomplished. Additionally, the PI met with the Interim Institutional Official, the College of Veterinary Medicine Dean and Associate Dean for Research and Graduate Affairs.

OLAW appreciates the prompt consideration of this matter by the University of Georgia which is consistent with the philosophy of institutional self-regulation. OLAW expects continuing post-approval monitoring to prevent recurrence of this non-compliance and potential associated animal welfare concerns. Based on the information provided, OLAW is satisfied that appropriate steps have been taken to investigate this incident and to attempt to prevent recurrence.

We appreciate being informed of this matter and please contact us with any further questions or concerns.

Sincerely,

(b) (6)

Nicole Lukovsky-Akhsanov, DVM, MPH, DACLAM
Division of Compliance Oversight
Office of Laboratory Animal Welfare

CC: IACUC contact



UNIVERSITY OF
GEORGIA

OFFICE OF RESEARCH

147 Paul D. Coverdell Center for Biomedical and Health Sciences
Athens, GA 30602
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July 28, 2021

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 reported to OLAW in a preliminary report on June 22. Due to a pattern of non-compliance within a single laboratory, the IACUC developed a remedial action plan.

This work is covered by an IACUC approved protocol and funded by the NIH under grant number 75N93019C00052.

The remedial action plan was completed on July 21.

- The PI was to develop and follow a written plan for maintaining compliance within the laboratory.
This was completed on July 5.
- The PI was to meet with the IACUC to describe how he intends to maintain compliance within the laboratory.
This was completed on July 21.
- The PI was to meet with the Interim Institutional Official, the College of Veterinary Medicine Dean, and Associate Dean for Research and Graduate Affairs.
This was completed on June 25.

At its scheduled meeting on July 21, the IACUC discussed the matter, determined that the response to the remedial action plan was adequate.

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)

Karen J. L. Burg, Ph.D.
Vice President for Research
Institutional Official

Cc: Dr. Leanne Alworth, Attending Veterinarian
Dr. Gaylen Edwards, IACUC Chair

(b) (6)

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, July 30, 2021 8:56 AM
To: Leanne Alworth
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: UGA Final to June Prelim

Thank you for this report, Dr. Alworth. We will send a response soon.

Axel Wolff, M.S., D.V.M.
Deputy Director, OLAW

From: Leanne Alworth <alworth@uga.edu>
Sent: Friday, July 30, 2021 8:29 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Gaylen L Edwards <gedwards@uga.edu>; (b) (6) Karen JL Burg <kburg@uga.edu>
Subject: UGA Final to June Prelim

Good morning,

In June, UGA provided a Preliminary Report (6/22) regarding a researcher's non-compliance and the actions the IACUC was requiring him to perform. He has completed those actions, and the Final Report is attached.

Please let me know if you have any questions.

Thanks
Leanne

Leanne Alworth, DVM, MS, DACLAM

Attending Veterinarian | Animal Care and Use

Office of Research | University of Georgia

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Office of Research
Animal Care and Use

June 22, 2021

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 preliminary report of a serious deviation from the PHS Policy that was identified on June 8, 2021. A researcher collected a volume of blood from mice that was more than what was approved on the protocol. Two of the mice died.

This work is covered by an IACUC approved protocol and funded by the NIH under contract number 75N93019C00052.

The IACUC discussed this event at its regularly scheduled June 16 meeting, as well as this lab's other recent non-compliance events with negative impacts on animals. The IACUC determined that action was required from the PI to demonstrate a plan to maintain compliance within the lab.

The following actions are required as the remedial action plan established to address the issue:

1. The PI will develop, and follow, a written plan for maintaining compliance within the laboratory. A Compliance Sustainability Plan template, with suggested options for the PI and lab personnel actions, was provided. (Template provided June 22)
2. The PI will meet with the IACUC to describe how he intends to maintain compliance within his laboratory. (Anticipated July 21)

3. The PI will meet with the Interim Institutional Official, the College of Veterinary Medicine Dean and Associate Dean for Research and Graduate Affairs. (Scheduled for June 25)

The IACUC will be notified about any updates on the remedial plan, at its next scheduled meeting on July 21. Once the remedial action plan is complete, a full report with an update on corrective action progress will be forwarded to you.

In the interim, please contact me if you have any questions or if you require additional information.

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)

Leanne Alworth, DVM, MS, DACLAM
Attending Veterinarian
Professor, Department of Population Health, College of Veterinary Medicine

Cc:

 (b) (6)

Dr. Gaylen Edwards, IACUC Chair

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, June 23, 2021 7:12 AM
To: Leanne Alworth
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Preliminary Report of non-compliance UGA

Thank you for this preliminary report, Dr. Alworth. We will open a new case file and look forward to receiving the final report from the IO after the IACUC has completed its investigation.

Axel Wolff, M.S., D.V.M.
Deputy Director, OLAW

From: Leanne Alworth <alworth@uga.edu>
Sent: Tuesday, June 22, 2021 5:17 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: (b) (6) Gaylen L Edwards <gedwards@uga.edu>; (b) (6)
(b) (6)
Subject: Preliminary Report of non-compliance UGA

Hello OLAW,

I am notifying you about a recent non-compliance incident at UGA. The attached report also explains the IACUC's handling of the incident in the context of previous incidents with the same laboratory.

Please let me know if you have any questions. I anticipate submitting a final report, or at least an update, after the July IACUC meeting.

Thank you,
Leanne

Leanne Alworth, DVM, MS, DACLAM
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