



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 10, 2021

Re: Animal Welfare Assurance
#A3152-01 (OLAW Case 1D)

James Weyhenmeyer, Ph.D.
Vice President for Research
Auburn University
(b) (4) Sanford Hall
Auburn University, AL 36849-0001

Dear Dr. Weyhenmeyer,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your August 30, 2021 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the Auburn University following up on an initial June 25, 2021 notification by email.

According to the information provided, this Office understands that the Auburn University Animal Care and Use Committee (ACUC) determined that instances of noncompliance occurred with respect to: the conduct of unapproved animal-related activities without prior IACUC review and approval. The final report states on June 24, 2021, the IACUC was notified that a principal investigator (PI) possibly used Avertin without prior IACUC approval when conducting a research procedure. In response, a subcommittee was formed to investigate the matter. The PI acknowledged that Avertin was used as an anesthetic agent in two mice without IACUC approval. In response, the IACUC issued a memorandum to the PI directing the immediate termination of the use of Avertin. Per the report, no adverse events were known to have occurred in these animals. The investigative results from the subcommittee were presented to the IACUC, and on July 15, 2021, the IACUC voted to implement the following actions:

- Suspend the PI from conducting any animal activities at Auburn University for a period of no less than nine months.
- Suspend the PI's IACUC protocols and transfer the animals to a holding protocol not administered by the PI.
- Require successful training on professionalism and integrity in research programs.
- Require successful retraining by completion of required IACUC training modules (online).
- Require successful retraining on the use of the primary rodent vivarium on the Auburn University campus.
- Require a post-assessment interview with members of the IACUC.

It is understood the PI submitted an appeal letter and the IACUC voted to decrease the suspension duration to no less than 6mo while maintaining the other requirements from the IACUC decision of July 15, 2021.

It is noted that this research is supported by PHS funding. Where applicable, please note that the PHS funding component must be notified directly of any suspension or termination of HHS (PHS) supported research. Based on its assessment of this explanation, OLAW understands that the Auburn University 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,

Jacquelyn

T. Tubbs -S

Digitally signed by Jacquelyn T.
Tubbs -S
Date: 2021.09.10 14:20:32 -0400

Jacquelyn Tubbs, DVM, DACLAM
Animal Welfare Program Specialist
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC Contact



AUBURN UNIVERSITY

OFFICE OF THE VICE PRESIDENT FOR
RESEARCH AND ECONOMIC DEVELOPMENT

August 30, 2021

Dr. Brent Morse
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare (OLAW)
6700B Rockledge Drive, Suite 2500, MSC 6910
Bethesda, MD 20892-7982

Assurance Number: D16-00092 (A3152-01)

Dear Dr. Morse,

We are providing a final report of noncompliance at Auburn University. The preliminary report was sent via email on June 25, 2021. The project is funded by NIH Grant 5R01HL125279-05.

On June 24, 2021, the IACUC received a report that Avertin had potentially been used without prior IACUC approval during conduct of a research procedure. An IACUC subcommittee was appointed to investigate the situation. The principal investigator (PI) confirmed that Avertin had been administered as an anesthetic agent to two mice without IACUC approval. The IACUC issued a memorandum to the PI directing the immediate cessation of use of Avertin. No adverse events are known to have occurred in these animals. After the subcommittee presented its findings to the committee, the IACUC discussed the incident.

At the IACUC meeting on July 15, 2021, the IACUC voted to:

- 1) Suspend the PI from conducting any animal activities at Auburn University for a period of no less than nine months
- 2) Suspend the PI's IACUC protocols and transfer the animals to a holding protocol not administered by the PI
- 3) Require successful training on professionalism and integrity in research programs
- 4) Require successful retraining by completion of required IACUC training modules (online)
- 5) Require successful retraining on the use of the primary rodent vivarium on the Auburn University campus
- 6) Require a post-assessment interview with members of the IACUC

After consultation with the Institutional Official, a letter indicating the above actions was sent to the PI.

An appeal letter was submitted to the IACUC by the PI on July 29, 2021. The letter was discussed at the IACUC meeting on August 5, 2021. The IACUC voted to reduce the suspension duration to no less than six months but maintain the other requirements from the IACUC decision of July 15, 2021.

Dr. Brent Morse
Page 2
August 30, 2021

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

Sincerely,

(b) (6)

James Weyhenmeyer, Ph.D.
Auburn University Institutional Official

(b) (6)

Terry Brandebourg, Ph.D.
Auburn University IACUC Chair

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Tuesday, September 7, 2021 6:20 AM
To: IACUC Admin
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: AU Final Report

Follow Up Flag: Follow up
Flag Status: Flagged

Thank you for this report, (b) (6) We will send a response soon.

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

From: IACUC Admin <OARPROG@auburn.edu>
Sent: Wednesday, September 1, 2021 1:17 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: James Weyhenmeyer <jweyhenmeyer@auburn.edu>; (b) (6) Terry Brandebourg <tdb0006@auburn.edu>
Subject: AU Final Report

Good afternoon,
Please see the attached final report from Auburn University (D16-00092/A3152-01).

If you have any questions or need additional information, please contact us at IACUCAdmin@auburn.edu.

Thank you,

(b) (6)

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AUBURN UNIVERSITY

OFFICE OF THE VICE PRESIDENT FOR
RESEARCH AND ECONOMIC DEVELOPMENT

June 25, 2021

Dr. Brent Morse
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare (OLAW)
6700B Rockledge Drive, Suite 2500, MSC 6910
Bethesda, MD 20892-7982

Assurance Number: D16-00092 (A3152-01)

Dear Dr. Morse,

We are providing a preliminary report of noncompliance at Auburn University.

Currently we are aware of the following: On June 24, 2021, the IACUC received a report that Avertin had potentially been used without prior IACUC approval during conduct of a research procedure. On June 25th, the principal investigator (PI) confirmed that Avertin had been administered as an anesthetic agent to two mice without IACUC approval. No adverse events are known to have occurred in these animals.

The IACUC issued a memorandum to the PI directing that the unapproved use of Avertin must stop immediately.

The IACUC has formed a subcommittee to gather and review all details surrounding this situation. Since our investigation of this incident is in its initial stages, we are still determining if there is an external funding component. If a funding component is found to be associated with this activity, we will report our findings to all applicable parties.

Once the investigation is completed, the subcommittee report will be presented to and discussed by the IACUC during full committee review and then a summary of findings with declaration of corrective actions taken will be reported to OLAW.

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

Sincerely,

(b) (6)

James Weyhenmeyer, Ph.D.
Auburn University Institutional Official

(b) (6)

Terry Brandebourg, Ph.D.
Auburn University IACUC Chair

202 Samford Hall, Auburn, AL 36849-5112; Telephone: 334-844-4784; Fax: 334-844-5971
auburn.edu/research

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, June 28, 2021 7:13 AM
To: IACUC Admin
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: AU Preliminary Report

Thank you for this preliminary report, (b) (6). 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: IACUC Admin <OARPROG@auburn.edu>
Sent: Friday, June 25, 2021 11:52 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: James Weyhenmeyer <jweyhenmeyer@auburn.edu>; Terry Brandebourg <tdb0006@auburn.edu>; (b) (6)
(b) (6)
Subject: AU Preliminary Report

Good morning,
Please see the attached preliminary report from Auburn University (D16-00092/A3152-01).

If you have any questions or need additional information, please contact us at IACUCAdmin@auburn.edu.

Thank you,

(b) (6)

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