



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

February 11, 2020

Re: Animal Welfare Assurance  
A3295-01 [OLAW Case 4J]

Dr. Jane E. Strasser  
Associate Vice President  
University of Cincinnati  
Office of Research Compliance and  
Regulatory Affairs  
P.O. Box 210567  
Cincinnati, OH 45221-0567

Dear Dr. Strasser,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your January 21, 2020 letter responding to OLAW's December 12, 2019 request for additional information regarding an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of Cincinnati.

According to the information provided, OLAW understands that on the day the issue was identified, the Attending Veterinarian and clinical veterinarian both reviewed the issues, approved protocol and relevant practices with the responsible laboratory staff member. The Director of the IACUC Office followed up with the principal investigator (PI) in a subsequent meeting. The researchers involved in animal experiment on the protocol were given training on two occasions, one focused on laboratory and animal handling skills and the subsequent training reviewed assessment of pain and distress along with the mandate and procedure to promptly report concerns regarding animal health and well-being to veterinary staff.

OLAW appreciates the prompt consideration of this matter by University of Cincinnati, which is consistent with the philosophy of institutional self-regulation. Based on the information provided, OLAW is satisfied that appropriate steps have been taken to investigate this incident. 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



Jane Strasser, Ph.D.  
Senior Associate Vice President for Research  
Institutional Official  
University of Cincinnati  
PO Box 210663  
51 Goodman Drive  
540 University Hall  
Cincinnati, OH 45221-0663

Phone: (513) 558-5034  
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Jane.Strasser@uc.edu

January 21, 2020

Nicole Lukovsky-Akhsanov, DVM, MPH, DACLAM  
Division of Compliance Oversight  
Office of Laboratory Animal Welfare  
6700B Rockledge Drive, Suite 2500 MSC 6910  
Bethesda, Maryland 20817

RE: PHS Assurance No. D16-00190 / (A3295-01)

Please find below my response to the queries contained in your December 12, 2019.

- 1) Was the PI and laboratory staff member retrained on the appropriate IACUC procedures?

On the day that the issue was identified the AV and Clinical Veterinarian both reviewed the issues, the approved protocol, and the relevant practices with the laboratory staff member. The Director of the IACUC Office followed up with the PI in a subsequent meeting.

- 2) Was the PI and laboratory staff members retrained to recognize poor physical condition of animals, post-procedure monitoring and mechanism of reporting clinical concerns to veterinary staff.

The researchers involved in animal experimentation on this protocol were given training on 2 occasions. One training focused on laboratory and animal handling skills. Subsequent training reviewed the assessment of pain and distress as well as the mandate and process to promptly report concerns with animal health and well-being to veterinary staff.

**Species:** mouse  
**NIH/NEHS Funding:** P30 ESO06096

Sincerely,

 (b) (6)

Jane E. Strasser, Ph.D.

cc: George Babcock, Ph.D., Chair, Institutional Animal Care and Use Committee

*An affirmative action/equal opportunity institution*



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Office of Laboratory Animal Welfare  
6700B Rockledge Drive, Suite 2500  
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Facsimile: (301) 402-7065

December 12, 2019

Re: Animal Welfare Assurance  
A3295-01 [OLAW Case 4J]

Dr. Jane E. Strasser  
Associate Vice President  
University of Cincinnati  
Office of Research Compliance and  
Regulatory Affairs  
P.O. Box 210567  
Cincinnati, OH 45221-0567

Dear Dr. Strasser,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your November 19, 2019 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of Cincinnati.

According to the information provided, OLAW understands that on October 1, 2019, during routine health observations the veterinary staff identified one dead mouse and nine other mice in poor physical condition. The principal investigator (PI) and the laboratory staff member were contacted and discovered that a drug has been administered via oral gavage, twice daily that was not described in the protocol. The veterinary staff instructed the researcher to immediately euthanize the remaining mice. Necropsies revealed that two mice had an esophageal perforation. The study is supported by PHS funding.

As a corrective measure, the researcher and lab manager met for retraining on October 3, 2019 with veterinary staff. The PI was requested to submit an amendment to the protocol to address the route and frequency of drug administration along with other applicable study design options. Furthermore, a letter was sent from the IO to the PI to acknowledge corrective action that had been taken to bring the issue into compliance.

OLAW appreciates the prompt consideration of this matter by the University of Cincinnati which is consistent with the philosophy of institutional self-regulation. Based on the information provided, OLAW requests further information as follows:

- Was the PI and laboratory staff member retrained on appropriate IACUC procedures?
- Was the PI and laboratory staff members retrained to recognize poor physical condition of animals, post-procedure monitoring and mechanisms of reporting clinical concerns to veterinary staff?

We appreciate being informed of this matter and look forward to your responses to the additional information request by **January 31, 2020**. 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



A3295-45

Jane Strasser, Ph.D.  
Associate Vice President for Research  
Research Integrity Officer  
University of Cincinnati  
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540 University Hall  
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November 19, 2019

Brent Morse, D.V.M., DACLAM  
Interim-Director, Division of Compliance Oversight  
Office of Laboratory Animal Welfare  
6700B Rockledge Drive, Suite 2500 MSC 6910  
Bethesda, Maryland 20817

RE: PHS Assurance No. D16-00190 / (A3295-01)

In accordance with PHS Policy and the terms of our Assurance Statement, we are advising you of an issue of non-compliance discussed at the October 10, 2019 meeting of the University of Cincinnati Institutional Animal Care and Use Committee (IACUC).

**Protocol Deficiency – Route of Administration Not Described in Approved Protocol**

On October 1, 2019 during routine health observations, the vet staff identified one dead mouse and nine others in poor physical condition. The PI and laboratory staff member was contacted and it was discovered that drugs had been administered by a route (oral gavage) and frequency (twice daily) that was not described in the protocol. The vet staff instructed the researcher to immediately euthanize the remaining mice. Necropsies were performed and two mice had an esophageal perforation. The IACUC deliberation was as follows:

Corrective Actions:

- The PI was requested to amend the protocol to address the route and frequency of drug administration and other applicable study design options
- The IACUC recommended the researcher be retrained on oral gavage technique, which was completed by the veterinary staff on October 3, 2019
- A letter was sent from the IO to the PI acknowledging the corrective actions that had been taken to bring the issue into compliance

**Species:** mouse  
**NIH/NEHS Funding:** P30 ESO06096

Sincerely,

(b) (6)

Jane E. Strasser, Ph.D.  
Associate Vice President for Research and Institutional Official

cc: George Babcock, Ph.D., Chair, Institutional Animal Care and Use Committee

*An affirmative action/equal opportunity institution*

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

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Wednesday, November 20, 2019 8:03 AM  
**To:** Custer, David (custerda)  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: Reports of Non-Compliance from University of Cincinnati D16-00190 (A3295-01)

Thank you for these reports, Mr. Custer. We will send replies soon.

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

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**From:** Custer, David (custerda) <custerda@ucmail.uc.edu>  
**Sent:** Tuesday, November 19, 2019 1:15 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Cc:** Babcock, George (babcocgf) <babcocgf@ucmail.uc.edu>; Strasser, Jane (strassje) <strassje@ucmail.uc.edu>  
**Subject:** Reports of Non-Compliance from University of Cincinnati D16-00190 (A3295-01)

Dear Dr. Morse, *et.al.*,

Please see the attached letters of non-compliance from the Institutional Official of the University of Cincinnati.

**David A. Custer**  
Interim-Director, Animal Regulatory Compliance  
IACUC Office  
Office of Research Integrity  
University of Cincinnati  
P.O. Box 210572  
Cincinnati, OH 45221-0572  
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