



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

January 30, 2019

Re: Animal Welfare Assurance  
A3586-01 [OLAW Case IJ]

Dr. Toni M. Ganzel  
Interim Institutional Official  
Animal Care and Use Program  
University of Louisville  
323 E. Chestnut Street  
Louisville, KY 40202

Dear Dr. Ganzel,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your January 18, 2019 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of Louisville. According to the information provided, OLAW understands that on January 8, 2019, approximately 15 neonatal mice were found alive in a carcass cooler. The animals were subsequently appropriately euthanized. The laboratory that was responsible for the improper euthanasia was also found to be using a CO2 flow rate that was higher than that stated in the protocol and not in accordance with the 2013 AVMA Guidelines for the Euthanasia of Animals. It is understood that the protocol was not funded by the PHS.

The corrective and preventive actions included voluntary, hands-on training for all lab personnel responsible for euthanasia. The IACUC required a separate training session for the PI with the IACUC Chair and the Attending Veterinarian. The IACUC has also implemented a new policy which clearly states the acceptable methods and considerations for euthanasia of different species. The IACUC will also require all laboratory personnel responsible for euthanasia to attend a hands-on training session for all new Proposals and three-year renewal Proposals prior to approval.

OLAW believes that the corrective measures put in place by the University of Louisville are consistent with the provisions of the PHS Policy on Humane Care and Use of Laboratory Animals. We appreciate being informed of this matter and find no cause for further action by this office.

Sincerely,

(b) (6)

Brent C. Morse, DVM  
Director  
Division of Compliance Oversight  
Office of Laboratory Animal Welfare

cc: IACUC Contact

UNIVERSITY OF  
**LOUISVILLE**

Office of the Executive Vice President for Health Affairs

18 January 2019

Brent Morse, D.V.M.  
Director, Division of Compliance Oversight  
Office of Laboratory Animal Welfare  
National Institutes of Health  
Rockledge 1, Room 3615  
6705 Rockledge Drive  
Bethesda, MD 20817-7982

Dear Dr. Morse:

This letter reports an event that the University of Louisville Institutional Animal Care and Use Committee (IACUC) deemed to meet the requirement for "deviation," as defined by our "Assurance of Compliance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals" (No. **A3586-01**).

Following a Report of Concern, the IACUC conducted an investigation into concerns regarding the euthanasia of mice. On January 8, 2019, laboratory personnel did not confirm the deaths of approximately 15 neonatal mice. The animals were discovered still alive in the carcass cooler by Research Resources Facilities staff, who promptly euthanized them in accordance with the 2013 AVMA Guidelines for the Euthanasia of Animals. During the investigation, the IACUC also learned that the laboratory was utilizing a higher CO2 flow rate not in accordance with the approved IACUC Proposals (15380, 18246) or the 2013 AVMA Guidelines for the Euthanasia of Animals. The Principal Investigator agreed to a voluntary hands-on euthanasia training for all laboratory personnel responsible for euthanasia in his lab conducted by Research Resources veterinary faculty at the suggestion of our Attending Veterinarian while the IACUC conducted its investigation. This training was completed on January 10, 2019. The IACUC has required that the PI attend a separate training session with the IACUC Chair and Attending Veterinarian. The IACUC has also implemented a new policy, "Euthanasia of Research Animals," which clearly states the acceptable methods and considerations for euthanasia of different species. In addition, the IACUC will require all laboratory personnel responsible for euthanasia to attend a hands-on training session for all new Proposals and three-year renewal Proposals prior to approval. *Note that records indicate that this study is not supported by federal funds.*

The IACUC has reminded the Principal Investigator that future incidents of non-compliance could result in limits on his authorization to perform work with animal subjects. We believe that the IACUC's response to these incidents was appropriate and will serve to safeguard the animals' welfare and the institution's regulatory compliance.

Sincerely,

(b) (6)

Toni M. Ganzel, M.D., M.B.A.  
Interim Institutional Official, Animal Care and Use Program

Cc: George M. Pantalos, Ph.D., IACUC Chair  
Leslie C. Sherwood, D.V.M., Attending Veterinarian  
File

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**Morse, Brent (NIH/OD) [E]**

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Thursday, January 24, 2019 8:39 AM  
**To:** Sherwood,Leslie C; OLAW Division of Compliance Oversight (NIH/OD)  
**Cc:** Institutional Animal Care and Use Commit,Service Account; Pantalos,George;  
Ganzel,Toni Michelle  
**Subject:** RE: Report of Noncompliance

Thank you for providing this report Dr. Sherwood. 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:** Sherwood,Leslie C [mailto:leslie.sherwood@louisville.edu]  
**Sent:** Wednesday, January 23, 2019 3:21 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Cc:** Institutional Animal Care and Use Commit,Service Account <iacuc@louisville.edu>; Pantalos,George <george.pantalos@louisville.edu>; Ganzel,Toni Michelle <toni.ganzel@louisville.edu>  
**Subject:** Report of Noncompliance

Dear Dr. Morse,

Please see the attached report of noncompliance. Thank you for your assistance.

Best,

Leslie

Leslie C. Sherwood, DVM

University Attending Veterinarian  
Assistant Vice President for Research Services  
Director, Research Resources Facilities  
Associate Professor

Office: (b) (6)  
Cell: (b) (6)