



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

September 5, 2019

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

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 August 23, 2019 letter reporting two instances 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 the first incident on May 6, 2019 involved five mice that had undergone unapproved survival surgeries for implantation of SQ minipumps. The mice had been administered a post-operative analgesic (carprofen) for at least 48 hours post-surgery, in accordance with IACUC policy. It is understood that the study was at least partially funded by the NIH.

The laboratory was required by the IACUC to attend a training session with the IACUC Chair and the Attending Veterinarian. The PI was counseled by the IACUC and encouraged to evaluate staff training and determine whether additional review of IACUC policies is necessary.

The second incident involved an August 13, 2019 self-report by an Investigator that a member of the laboratory did not confirm the deaths of two neonatal pups and the animals were discovered alive in the carcass cooler. They were promptly euthanized. It is understood that the study was at least partially funded by the NIH.

All members of the laboratory were required by the IACUC to attend a hands-on euthanasia training session. The responsible laboratory member must be observed by Research Resources Facilities veterinary staff the first two times that euthanasia is performed after the training.

OLAW believes that the corrective and preventive 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 understand that any unauthorized costs will not be charged to NIH grants. 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

August 23, 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 two events 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).

1. Following a Report of Concern, the IACUC investigated concerns regarding five mice subjected to a survival surgical procedure under IACUC *Proposal* 16684. The Committee determined that on May 6, 2019, five mice underwent a survival surgical procedure to implant an SQ minipump that was not previously approved by the IACUC. Anesthesia and surgical records provided by the laboratory indicated that the mice received postoperative analgesia (carprofen) immediately after surgery for a total duration of at least 48 hours, in accordance with the IACUC policy "Use of Postoperative Analgesia." *Note that records indicate that this study was at least partially supported by federal funds* (2R01HL074185-11), "Reversing diabetic muscle myopathy by exercise and exosomes").

After taking the laboratory's recent staffing changes and commendable history of laboratory inspections into consideration, the IACUC has required that the laboratory attend a training session with the IACUC Chair and Attending Veterinarian. The IACUC has also encouraged the Principal Investigator to evaluate staff training and determine whether additional review of IACUC policies is necessary. The IACUC reminded the PI that future incidents of non-compliance could result in limits on the laboratory's authorization to perform work with animal subjects.

2. On August 13, 2019, an Investigator self-reported to the IACUC that a member of the laboratory did not confirm the deaths of two neonatal pups under IACUC *Proposal* 18188. The animals were discovered 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*. *Note that records indicate that this study was at least partially supported by federal funds* (R01-CA180986-01A1, "Prevention of breast cancer development by epidermal fatty acid binding protein"; R01-CA177679-01A1, "The role of adipocyte/macrophage fatty acid binding protein in breast cancer development"; 5P30GM106396-05, "Screening compounds by targeting E-FABP for cancer therapy").

The Committee believes this was an isolated incident in the laboratory. However, due to the gravity of the oversight the IACUC has required that all members of the laboratory attend a hands-on euthanasia training session with RRF veterinary staff. In addition, the member of the laboratory who did not utilize a secondary method of euthanasia must be observed by RRF veterinary staff the first two times that euthanasia is performed after the training.

The IACUC has reminded the PIs that future incidents of non-compliance could result in limits on their laboratories' authorization to perform work with animal subjects. We believe that the IACUC's response to these incidents was appropriate and will serve to safeguard animal welfare and the institution's regulatory compliance. The UofL Office of Grants and Contracts will assist the PIs in ensuring that any unauthorized costs initially billed to NIH grants will be covered by other sources. Please note that a similar report has been filed with AAALAC International.

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  
Judy Bristow, Director, Sponsored Programs Administration  
File

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

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Tuesday, September 03, 2019 3:36 PM  
**To:** Institutional Animal Care and Use Commit,Service Account; OLAW Division of Compliance Oversight (NIH/OD)  
**Cc:** Sherwood,Leslie C; Pantalos,George; Ganzel,Toni Michelle; Bristow,Judy L.  
**Subject:** RE: Report of Noncompliance

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:** Institutional Animal Care and Use Commit,Service Account [mailto:iacuc@louisville.edu]  
**Sent:** Tuesday, September 03, 2019 3:19 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Cc:** Sherwood,Leslie C <leslie.sherwood@louisville.edu>; Pantalos,George <george.pantalos@louisville.edu>; Ganzel,Toni Michelle <toni.ganzel@louisville.edu>; Bristow,Judy L. <judy.bristow@louisville.edu>  
**Subject:** Report of Noncompliance

Dear Dr. Morse,

Please find the attached report of noncompliance. Please let me know if you have any questions or require additional information.

Best Regards,

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(b) (6)

UNIVERSITY OF  
**LOUISVILLE**