



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

December 20, 2019

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

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 December 12, 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, this Office understands that the University of Louisville Animal Care and Use Committee (ACUC) determined that instances of noncompliance occurred with respect to: mice that underwent femoral vein injections without protocol approval and mice that underwent toe clipping and ear notching without protocol approval. On November 22, 2019 it was reported that 6 mice received femoral vein injections and this procedure was not approved on the IACUC proposal. The corrective actions were: 1) the lab submitted a modification and obtained IACUC approval to perform the procedure. 2) the IACUC required that the laboratory attend a training session with Attending Veterinarian and Chair of the IACUC on adherence to IACUC proposals. It is noted that records indicate the study was at least partially supported by federal funds.

The second incident of noncompliance occurred on December 5, 2019. The IACUC received a self-report that one litter of pups underwent toe clipping and ear notching was performed on several occasions to weaning mice. The corrective action was the IACUC requiring the principal investigator and laboratory technician to attend a training session with the Attending Veterinarian and IACUC Chair on adherence to IACUC proposals. It is noted that records indicate the study was not supported by federal funds. Based on its assessment of this explanation, OLAW understands that the University of Louisville 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,

(b) (6)

Jacquelyn T. Tubbs, DVM  
Veterinary Medical Officer  
Division of Compliance Oversight  
Office of Laboratory Animal Welfare

cc: IACUC Contact

12 December 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 incidents that the University of Louisville Institutional Animal Care and Use Committee (IACUC) deemed to meet the requirement for "deviations," as defined by our "Assurance of Compliance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals" (No. A3586-01).

On 22 November 2019, the IACUC received a self-report that six mice underwent a survival surgery procedure involving a femoral vein injection which was not approved on the IACUC Proposal (18200). The laboratory has since submitted a modification and obtained IACUC approval to perform the procedure. The Principal Investigator was reminded that performing procedures without strict compliance with the IACUC-approved Proposal is expressly forbidden. In addition, the IACUC has required that the laboratory attending a training session on adherence to IACUC Proposals with the Attending Veterinarian and Chair of the IACUC. Note that records indicate that this study was at least partially supported by federal funds (1R01DK104653-01, "Hydrogen sulfide mechanism of renal hypertension").

On 5 December 2019, the IACUC received a self-report that mice underwent toe clipping and ear notching procedures which were not approved on the IACUC Proposal (17174). The Principal Investigator stated that toe clipping was performed on a single litter of pups, and the ear notching was performed on several occasions on weaning mice. The PI had a lengthy conversation with the laboratory technician who performed the procedures about conducting all work in accordance with the approved IACUC Proposal. Even so, the IACUC has required that the PI and laboratory technician attend a training session on adherence to IACUC Proposals with the Attending Veterinarian and Chair of the IACUC. Note that records indicate that this study was not supported by federal funds.

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 responses to these incidents was appropriate and will serve to not only safeguard the animals' welfare and, in so doing, the institution's regulatory compliance status, but also protect the PIs from additional sanctions should similar incidents occur.

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

(b) (6)

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

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Monday, December 16, 2019 6:41 AM  
**To:** (b) (6)  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: Report of Noncompliance

Thank you for this report, (b) (6) We will respond soon.

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

**From:** (b) (6)  
**Sent:** Friday, December 13, 2019 3:49 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,



**UNIVERSITY OF  
LOUISVILLE**