



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

March 24, 2020

Re: Animal Welfare Assurance  
A3586-01 [OLAW Case 1Q]

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 March 19, 2020 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 24, 2020 your institution determined that seven mice were used on a training protocol after the protocol had expired. The mice were used for anesthesia induction and recovery training only, then euthanized. No animal welfare concerns were identified. The issue was self-reported by the protocol PI. It is understood that the protocol was not funded by the PHS.

To help prevent and correct the issue, the designation of the PI for the training protocol has been changed to the clinical veterinarian who will be conducting the training. In addition, all personnel approved as project participants were required to attend a training session with the IACUC Chair and Vice Chair.

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. Although this activity was not PHS funded, the application of the expectations of the PHS Policy across the animal care and use program reduces any potential appearance of a double standard. 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**

A3586-1Q  
Toni M. Ganzel, M.D., MBA, FACS  
Dean of the School of Medicine  
Professor of Otolaryngology

March 19, 2020

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).

On January 24, 2020, the IACUC received a self-report from a Research Resources Facilities (RRF) veterinarian who was the Principal Investigator on a training *Proposal* (#16720). The training *Proposal* expired on January 18, 2020 and the renewal *Proposal* (#19640) was approved on January 24, 2020. During this interlude, on January 22, 2020, a training session was held for researchers on anesthesia induction and recovery. No experimental or other training procedures were performed. Seven mice were utilized during the session and were euthanized after completion of the training the same afternoon. To prevent future recurrences of this nature, the investigator has since submitted a Principal Investigator change request to the IACUC appointing the clinical veterinarian that performs the trainings as Principal Investigator.

The IACUC believes this is an isolated incident and that appropriate measures have been taken to prevent a recurrence. The Committee did not identify any immediate animal welfare concerns. However, to safeguard animal welfare the Committee has required that all personnel approved as project participants on *Proposal* 19640 attend a training session with the IACUC Chair and Vice Chair. *Note that records indicate that this study was not supported by federal funds.*

We believe that the IACUC's responses to this incident was appropriate and will serve to safeguard animal welfare and the institution's regulatory compliance status.

Sincerely,

(b) (6)

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

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

University of Louisville • Abell Administration Center • 323 East Chestnut Street • Louisville, KY 40292-1823  
P: 502-852-1499 F: 502-852-1484 E: louisville.edu/medschool

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

---

**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Friday, March 20, 2020 6:57 AM  
**To:** Institutional Animal Care and Use Commit,Service Account  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: Report of Noncompliance

Thank you for this report. We will send a response soon.

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

---

**From:** Institutional Animal Care and Use Commit,Service Account <iacuc@louisville.edu>  
**Sent:** Thursday, March 19, 2020 3:13 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Cc:** Ganzel,Toni Michelle <toni.ganzel@louisville.edu>; Sherwood,Leslie C <leslie.sherwood@louisville.edu>;  
Pantalos,George <george.pantalos@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,

(b) (6)

(b) (6)