



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

June 11, 2019

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

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 20 May 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 a PI indicated that mice that had undergone survival surgeries for brain tumor implantation had not been administered post-operative analgesics as required by the protocol. It is understood that the protocol was at least partially funded by the PHS.

The PI was counseled and was also required by the IACUC to attend a training session on analgesic use and perioperative record keeping.

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. For future reports, please indicate the approximate number of animals involved in the incident. 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.**

SCHOOL OF MEDICINE

20 May 2019

A3586-1L  
Toni M. Ganzel, MD, MBA  
Dean of the School of Medicine  
Professor of Otolaryngology

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 one finding 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).

During the laboratory inspections conducted during the most recent semiannual self-assessment, a PI indicated that mice had undergone survival surgeries for brain tumor implantation and did not receive post-operation analgesia in accordance with the approved IACUC *Proposal* (17158). Analgesia use logs did not reflect IACUC approved use of analgesia. The PI was reminded that performing procedures without strict compliance with the IACUC-approved *Proposal* is expressly forbidden. In addition, the IACUC has required that the PI attend a training session on analgesic use and perioperative record keeping with the Attending Veterinarian and Chair of the IACUC. *Note that records indicate that this study was at least partially supported by federal funds* (7R01NS081125-04, "TRANSFER: Aurora A is a Novel therapeutic target in glioblastoma").

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  
Eyas M. Hattab, M.D., M.B.A., Chair, Department of Pathology & Laboratory Medicine  
File

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

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Monday, June 03, 2019 12:05 PM  
**To:** Sherwood, Leslie C; OLAW Division of Compliance Oversight (NIH/OD)  
**Cc:** Ganzel, Toni Michelle; Institutional Animal Care and Use Commit, Service Account; Pantalos, George  
**Subject:** RE: Report of Noncompliance

Thank you for sending 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:** Friday, May 31, 2019 1:51 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Cc:** Ganzel, Toni Michelle <toni.ganzel@louisville.edu>; Institutional Animal Care and Use Commit, Service Account <iacuc@louisville.edu>; Pantalos, George <george.pantalos@louisville.edu>  
**Subject:** Report of Noncompliance

Dear Dr. Morse,

Please find a letter attached detailing a report of noncompliance that our IACUC discovered during our most recent semi-annual program review and inspections. The training session with myself and our IACUC Chair described in the letter occurred this morning with the PI and laboratory staff. Please let me know if you have any questions or require additional information.

Best,

Leslie

Leslie C. Sherwood, DVM

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

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