



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

February 26, 2020

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

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 February 20, 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 five mice failed to receive pre-operative analgesia as stated in the protocol. The mice were observed to be distressed following the tumor resection procedure. It was determined that the surgery had been conducted under a different protocol.

The immediate action taken upon discovery consisted of providing analgesia to the mice. The protocol was amended to include the surgery, the laboratory staff was counseled and retrained on the requirement to follow the protocol, and summary forms are now used outlining the approved procedures.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to correct and prevent recurrence of this problem. OLAW concurs with the actions taken by the institution to comply with the PHS Policy.

Sincerely,

(b) (6)

Axel Wolff, M.S., D.V.M.
Deputy Director
Office of Laboratory Animal Welfare

cc: IACUC Chair

February 20, 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 29, 2020, the IACUC received a self-report from an investigator after a deviation from the IACUC-approved *Proposal* (#19537) was identified. On January 13, 2020, an animal health concern was reported by RRF veterinary staff who identified 5 hyper-responsive post-operative mice. An RRF veterinarian, in conjunction with the surgeon who performed the tumor resection procedure on the mice, discovered that analgesia was not administered to the animals preoperatively as described in the IACUC-approved *Proposal*. Analgesics were immediately administered to the animals. The laboratory then reviewed the IACUC *Proposal* and discovered that the tumor resection procedure was approved in another *Proposal* (#18261), but not the *Proposal* that the animals receiving the surgical procedure were assigned to. On January 14, 2020, the laboratory submitted a modification to the IACUC to add the procedure to the *Proposal* (#19537) and also requested a meeting with RRF veterinary faculty. During the meeting on January 16, 2020, RRF faculty and the laboratory discussed the importance of adherence to the IACUC-approved *Proposal* and the deviation in question. The laboratory has since taken measures to prevent recurrences by preparing summary forms that detail procedures listed on approved IACUC *Proposals* and posting them for easy access to all members in the laboratory.

The IACUC took into consideration the laboratory's outstanding record of compliance over the last 20 years and the measures enacted by the lab to protect animal welfare. However, due to the gravity of the oversight, the Committee has required that all members of the laboratory attend a training session with the IACUC Chair and Attending Veterinarian on compliance and adherence to an IACUC-approved *Proposal*. *Note that records indicate that this study was not supported by federal funds.*

The IACUC has reminded the PI that future incidents of non-compliance could result in limits on their lab's authorization to perform work with animal subjects. We believe that the IACUC's responses to this incident was appropriate and will serve to safeguard the animals' welfare and the institution's regulatory compliance status, as well as protect the PIs from additional sanctions should similar incidents occur.

Sincerely,

(b) (6)

Toni M. Ganzel, MD, MBA
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]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, February 26, 2020 7:12 AM
To: Institutional Animal Care and Use Commit,Service Account
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Report of Noncompliance

Thanks, we'll use this version.

From: Institutional Animal Care and Use Commit,Service Account <iacuc@louisville.edu>
Sent: Tuesday, February 25, 2020 3:57 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: RE: Report of Noncompliance
Importance: High

Dear Dr. Morse,

Please find the attached corrected report of noncompliance. The previously stated funding information was incorrect; this study was not supported by federal funds. Please let me know if you have any questions or require additional information.

Best Regards,

(b) (6)



From: (b) (6)
Sent: Tuesday, February 25, 2020 1:36 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,

(b) (6)

(b) (6)

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, February 26, 2020 7:07 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 send a response soon.

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

From: (b) (6)
Sent: Tuesday, February 25, 2020 1:36 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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