



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

November 20, 2018

Re: Animal Welfare Assurance
A3079-01 [OLAW Case 3Q]

Dr. Dawn A. Bonnell
Vice Provost for Research
University of Pennsylvania
1 College Hall, (b) (4)
Philadelphia, PA 19104-6303

Dear Dr. Bonnell,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your November 13, 2018 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of Pennsylvania. According to the information provided, OLAW understands that one mouse was subjected to a tail snip for genotyping without anesthesia, more tissue was taken than outlined in institutional guidelines, and one individual was not listed on the protocol.

The immediate action taken upon discovery consisted of providing analgesics for the mouse. The corrective actions consisted of stopping additional tissue collection/genotyping, counseling the Principal Investigator and laboratory staff, and amending the protocol to include the individual.

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
Dr. Gregory Reinhard, D.V.M., Director of Animal Welfare



Office of the Vice Provost for Research

November 13, 2018

Axel V. Wolff, MS, DVM
Deputy Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
RKL 1, Suite 360, MSC 7982
6705 Rockledge Drive
Bethesda, MD 20892-7982

University of Pennsylvania

A3079-01

Dear Dr. Wolff,

We wish to report an incident involving a procedure performed on a single mouse which was not approved in the IACUC protocol. Furthermore, the "off protocol" procedure was not performed in manner consistent with our IACUC guidelines for this procedure and one of the researchers involved in the study was not listed on the protocol.

The specifics of the incident were when the laboratory members attended a seminar on mouse genetic typing and then decided to take advantage of a free genotyping offer. The researchers collected a tail tissue sample from a single mouse. The amount of material collected was larger than the Penn IACUC Guidelines on *Mouse and Rat Genotyping Methods* and the mouse was not anesthetized as required by the Guidelines. Assisting in the study was a researcher that was not listed on the protocol. However, this researcher had completed all the required IACUC training. The mouse was noticed later that day by the animal care staff and a veterinary service staff member provided the proper medical analgesics. A clinical veterinarian contacted the laboratory and the IACUC Compliance team about a potential non-compliance related to the sample collection. The laboratory stopped any further sampling. The IACUC Compliance staff member investigated the incident and notified the IACUC Compliance Committee.

The IACUC compliance liaison member investigated and noted the aforementioned non-compliance items. The PI was informed on the compliance gaps and was very responsive to address the gaps. The PI and laboratory manager immediately addressed the issues with the laboratory staff. The protocol was amended to include the new researcher and the laboratory decided that genotyping is not needed for this study. The IACUC Chairperson, an IACUC Compliance Liaison person and the Assistant director the IACUC Administration met with entire laboratory and reviewed the importance of animal welfare, and the importance of staff knowing the content of their IACUC protocols and keeping them up-to-date. The IACUC Compliance

Subcommittee and the IACUC were informed of the incident and the corrective actions. The grant associated with study was 5R21AI128569.

Please feel free to contact me if you have any questions.

Sincerely yours,

(b) (6)

Dawn Bonnell, PhD
Vice Provost for Research
Trustee Professor of Materials Science and Engineering
Institutional Official

CC: IACUC Chair, University of Pennsylvania
Attending Veterinarian and ULAR Director, University of Pennsylvania
Director of Animal Welfare, University of Pennsylvania

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Thursday, November 15, 2018 2:08 PM
To: Reinhard, Gregory R; OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Penn Non-Compliance Reporting

Thank you for 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: Reinhard, Gregory R [mailto:reingr@upenn.edu]
Sent: Thursday, November 15, 2018 12:53 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: Penn Non-Compliance Reporting

Attached please find a non-compliance issue that occurred at the University of Pennsylvania (A3079-01). The correction of the issue was overseen by the IACUC's Compliance Subcommittee.

Please feel free to contact me if you have any questions.

Regards,
Gregory Reinhard

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