



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, MD 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

June 17, 2020

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

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 June 10, 2020 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of Pennsylvania. This letter had not been preceded by a preliminary report to OLAW.

According to the information provided, this Office understands that the University of Pennsylvania Animal Care and Use Committee (ACUC) determined that instances of noncompliance occurred with respect to: failure to adhere to the IACUC-approved protocol. The final report states that the research team did not monitor nor remove rear leg bandages on 3 laboratory mice as per protocol. It is stated the lack of monitoring and removal of bandages contributed to a medical adverse event. As a result, the mice were humanely euthanized and the vet staff and IACUC were informed of the issues by the principal investigator (PI). To avoid future recurrence, the PI agreed to: retraining the staff, enhancing the monitoring and lengthening the monitoring period. Also, a more vigorous documentation practice was adopted which includes confirmation of bandage actions.

It is noted that this research is supported by PHS funds. This Office assumes that the IACUC approved the corrective action plan. Based on its assessment of this explanation, OLAW understands that the University of Pennsylvania 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,

Jacquelyn T. Tubbs -S
Digitally signed by
Jacquelyn T. Tubbs -S
Date: 2020.06.18
08:45:59 -04'00'

Jacquelyn T. Tubbs, DVM
Animal Welfare Program Specialist
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC contact



Office of the Vice Provost for Research

June 10, 2020

Dr. Brent Morse
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
Case PP120

Dear Dr. Morse,

The University of Pennsylvania is reporting an adverse event that affected the well-being of three laboratory mice on an IACUC approved skin research project. The research team did not monitor nor remove a rear leg bandage as per protocol which contributed to a medical adverse event. When the medical issue was noted, the mice were humanely euthanized and the veterinarian staff and IACUC were informed of the issues by the PI. To avoid future incidents, the PI agreed to retrain the staff, the monitoring was enhanced, and the monitoring period lengthened. Additionally, a more robust documentation practice was adopted which includes confirmation of bandage actions. The grant was funded by NIH 5 K08 AI 130365 02.

Sincerely,

(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

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, June 12, 2020 7:08 AM
To: Reinhard, Gregory R
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Adverse Event (Noncompliance) Report

Thanks Greg. We'll respond soon.
Axel Wolff

From: Reinhard, Gregory R <reingr@upenn.edu>
Sent: Wednesday, June 10, 2020 11:43 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: Adverse Event (Noncompliance) Report

Dr. Morse
Attached please find a adverse event (noncompliance) report from the University of Pennsylvania.
Regards,
Gregory Reinhard

Gregory R. Reinhard, MBA, DVM, DACLAM, CPIA
Director of Animal Welfare
University of Pennsylvania
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Philadelphia, PA 19104
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