



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

May 23, 2023

Re: Animal Welfare Assurance
A3079-01 [OLAW Case 4L]

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

Dear Dr. Bonnell,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your May 4, 2023, letter reporting an adverse event at the University of Pennsylvania. The letter had not been preceded by a preliminary report to OLAW.

According to the information provided and follow-up telecommunication, OLAW understands that the University of Pennsylvania IACUC determined that there was an unexplained increase in morbidity and mortality during a research study. During fall 2022, a researcher reported increased morbidity and mortality among a group of mice during a research study. While the orally-administered agent used during the study had historically caused minor or no illness, 35 mice died or were humanely euthanized during this time.

The researcher, veterinarian, and the Office of Animal Welfare reviewed the event but were unable to determine the cause. Enhanced monitoring records were implemented, to compliment an already enhanced monitoring schedule.

Based on the information provided, OLAW understands that the University of Pennsylvania has implemented measures reduce the likelihood of recurrence. Your prompt and thorough resolution of this matter is commendable and consistent with the PHS Policy philosophy of monitored self-regulation. We appreciate having been informed of these matters and find no cause for further action by this Office.

Sincerely,

Megan Clark DVM, MPH, CPIA
Animal Welfare Program Specialist
Office of Laboratory Animal Welfare

cc: IACUC contact



Office of the Vice Provost for Research

Brent Morse DVM
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

May 4, 2023

Dr. Morse,

The University of Pennsylvania would like to report an adverse event. The researcher reported to the IACUC that a group of mice in an IACUC-approved infectious disease study had an increase in morbidity and mortality. The orally administered agent usually causes only minor or no illness; however, in one study of thirty-eight mice, thirty-five died or were humanely euthanized during the study. The researcher and a staff veterinarian reviewed the event but were not able to identify the exact cause of the adverse event. The Office of Animal Welfare reviewed the case. It noted that the animal monitoring exceeded the IACUC protocol requirements and provided feedback to the research staff on how to enhance monitoring records. The researcher will immediately contact the veterinary staff if there are any future adverse events. The study was funded by grants 1-R01-AI-139102-01A1 and 1R21AI163596-01A1.

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



Office of the Vice Provost for Research

McCoy, Devora (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Thursday, May 11, 2023 11:48 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Adverse event report

Good morning (b) (6)

Thank you for sending us this report, assigned OLAW case number A3079-4L, and we will send an official response soon.

Best,
Devora

Devora McCoy, BS, MBA ([pronunciation](#))
Program Analyst
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health

Phone: 301-435-2390
Email: devora.mccoy@nih.gov

From: (b) (6)
Sent: Wednesday, May 10, 2023 5:20 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: [EXTERNAL] Adverse event report

I am attaching an adverse event report from the University of Pennsylvania.
Please contact me, if you have any questions.

Regards

(b) (6)