



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

October 10, 2018

Re: Animal Welfare Assurance
A3077-01 [OLAW Case 40]

Ms. Robyn Diaz
Senior Vice President and Chief Legal Officer
St. Jude Children's Research Hospital
262 Danny Thomas Place, MS 400
Memphis, TN 38105-2794

Dear Ms. Diaz,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your October 8, 2018 letter reporting a serious deviation from the provisions of the *Guide for the Care and Use of Laboratory Animals* at St. Jude Children's Research Hospital, following up on an initial report on August 13, 2018. According to the information provided, OLAW understands that three mice died and one required euthanasia due to hypoxia caused by incorrect assembly of a cage on a biocontainment caging unit (BCU), which resulted in lack of supply air and exhaust.

The corrective actions consisted of counseling the Principal Investigator to ensure adequate staffing, to have a second person check that all cages are correctly assembled and placed on the rack, and to retrain the laboratory staff on correct use of the BCU.

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 on Humane Care and Use of Laboratory Animals.

Sincerely,

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

cc: IACUC Chair



Robyn Diaz
Chief Legal Officer, Senior Vice President
Office of Legal Services

t 901.595.2288 f 901.595.5944
robyn.diaz@stjude.org

October 8, 2018

Axel Wolff, DVM
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare/NIH
RKL1, Suite 360, MSC 7982
6705 Rockledge Dr.
Bethesda, MD 20892-7982

Subject: Report of Noncompliance/Animal Welfare Assurance D16-00043 (A3077-01)

Dear Dr. Wolff:

Please accept this written report which documents an incident of noncompliance with Public Health Service (PHS) policy governing the care and use of laboratory animals. A description of the incident and the corrective actions taken to prevent the recurrence of a similar incident of noncompliance are provided below.

On Friday June 29, 2018, while performing daily observations of the animals in the ABSL-3+ facility, a biocontainment technician found four mice dead that were housed in a ventilated biocontainment caging unit (BCU). One mouse was still alive; however, it was later euthanized due to its condition. The deaths of the animals were reported to the Principal Investigator (PI), who reported it to the Chair of the ACUC, who subsequently appointed a subcommittee of the ACUC to investigate the incident.

The subcommittee of the ACUC met on July 9, 2018 to investigate the death of the mice and interviewed the ARC Manager of Biosafety and Biocontainment, the PI and the research laboratory specialists who worked in the room the day before the discovery. The subcommittee learned that the research laboratory specialist entered the biocontainment facility on June 28, 2018 and weighed approximately twenty-four cages of mice that day. All the mice were housed in a BCU. Each cage in the BCU is designed with an airtight seal to prevent the release of bio-hazardous materials administered to the animals. The system provides HEPA filtered supply air and exhaust to each cage through two check valves on the cage that fit into matching ports on the rack. When the cage is removed from the rack, the check valves close and the cage becomes airtight. Immediately after removing each cage from the rack, the research laboratory specialist took each cage to a biological safety cabinet and opened the cage to weigh the mice. After weighing the mice in each of twenty-four cages, she replaced the top on each cage and returned it to the rack. She failed to recognize that one of the cages was assembled incorrectly. As a result, supply air and exhaust were not provided to the cage and the mice became hypoxic and died. The research laboratory specialist did not realize that she had assembled the cage incorrectly prior to returning it to the rack.

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Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Tuesday, August 14, 2018 8:21 AM
To: Schultz-Cherry, Stacey; OLAW Division of Compliance Oversight (NIH/OD)
Cc: (b) (6) Degrace, Marciela (NIH/NIAID) [E]; Rahija, Richard J
Subject: RE: Report

Thank you for this report Dr. Schultz-Cherry. We will open a case file and await your final report.

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: Schultz-Cherry, Stacey [mailto:Stacey.Schultz-Cherry@STJUDE.ORG]
Sent: Monday, August 13, 2018 4:04 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: (b) (6) Degrace, Marciela (NIH/NIAID) [E] <marciela.degrace@nih.gov>; Rahija, Richard J <Richard.Rahija@STJUDE.ORG>
Subject: Report

Dear OLAW Division of Compliance Oversight,
 I am writing to let you know that the St Jude Children's Research Hospital ACUC investigated an incorrectly assembled cage in a biocontainment caging unit that occurred in July 2018 and was deemed reportable. The animals involved were on a PHS-funded award. The report is forthcoming. Please feel free to contact me if you need additional information. Thank you in advance for your attention.

Best,

Stacey Schultz-Cherry, PhD
 Member, Department of Infectious Diseases
 St. Jude Children's Research Hospital
 Memphis, TN 38105

Phone: (b) (6)

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St. Jude Children's
 Research Hospital
 Graduate School of
 Biomedical Sciences

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