



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE  
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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

DATE: July 11, 2022

TO: Michael M. Gottesman, M.D.  
Deputy Director for Intramural Research, NIH

FROM: Senior Animal Welfare Program Specialist, Office of Laboratory Animal Welfare

SUBJECT: Animal Welfare Investigation (NIAID-RML #20-22) - Animal Welfare Assurance  
A4149-01 [Case 17B]

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your June 10, 2022 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the NIH Intramural Research Training Program. This letter had not been preceded by a preliminary report to OLAW.

According to the information provided, this Office understands that the NIAID-RML Animal Care and Use Committee (ACUC) determined that instances of noncompliance occurred with respect to conditions that jeopardized the health/well-being of animals resulting in harm to animals. The animal incident report states there was a miscommunication during the transfer of 8 cages of mice between buildings. This miscommunication resulted in valves not being properly installed into Hydropac pouches. The next day, the mice were infected as approved in the ASP and the daily health check occurred. The animals began to exhibit clinical signs which could be interpreted as possible dehydration or signs consistent with the study parameters. An animal technician discovered the valves were not properly installed and provided water/gel, along with notifying a clinical veterinarian of the incident. It is stated one mouse was euthanized but the other remaining animals were observed eating and drinking. Ultimately, the decision was made to euthanize all the animals.

The following corrective actions were implemented in response to the incident:

- The SOP regarding animal transfer has been updated.
- The SOP regarding rodent animal room and health checks has been updated.
- Animal care staff read and signed off on the updated SOPs.
- Animal care staff received documented training on proper water pouch placement.
- The research group will include checks for food/water during health checks.

Based on its assessment of this explanation, OLAW understands that the NIH Intramural Research Training Program 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.

Page 2 – Dr. Gottesman  
July 11, 2022  
OLAW Case A4149-17B

Sincerely,  
Jacquelyn T.  
Tubbs -S

Digitally signed by Jacquelyn T.  
Tubbs -S  
Date: 2022.07.11 07:26:07  
-04'00'

Jacquelyn Tubbs, DVM, DACLAM  
Senior Animal Welfare Program Specialist  
Division of Compliance Oversight  
Office of Laboratory Animal Welfare

cc: Dr. Stephen Denny  
Dr. Richard Wyatt  
Dr. Patrick Hanley

**McCoy, Devora (NIH/OD) [E]**

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**From:** McCoy, Devora (NIH/OD) [E]  
**Sent:** Monday, July 11, 2022 10:45 AM  
**To:** Gottesman, Michael (NIH/OD) [E]  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD); Denny, Stephen (NIH/OD) [E]; Wyatt, Richard G (NIH/OD) [E]; Hanley, Patrick (NIH/NIAID) [E]  
**Subject:** OLAW Case A4149-17B  
**Attachments:** OLAW Case A4149-17B.pdf

Good morning Dr. Gottesman,

Attached please find the final response to OLAW Case A4149-17B. If you have any questions, feel free to contact us by phone or by e-mail.

Best,  
Devora

Devora McCoy, BS, MBA  
Program Analyst  
Division of Compliance Oversight  
Office of Laboratory Animal Welfare  
National Institutes of Health  
301-435-2390

A4149-178



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health  
Bethesda, Maryland 20892

[www.nih.gov](http://www.nih.gov)

June 10, 2022

TO: Brent C. Morse, D.V.M.  
Director, Division of Compliance Oversight  
Office of Laboratory Animal Welfare

FROM: Deputy Director for Intramural Research, NIH

SUBJECT: Animal Welfare Investigations - Assurance D16-00602 (NIAID-RML 20-22)

This correspondence conveys the results of an animal incident investigation by the NIH National Institute of Allergy and Infectious Diseases-Rocky Mountain Laboratories (NIAID-RML) ACUC in accordance with Assurance D16-00602 and PHS Policy IV.F.3. The incident involved the failure of animal technicians to appropriately install valves into Hydropac pouches during mouse cage assembly. The failure contributed to the euthanasia of eight cages of mice upon discovery of this SOP noncompliance.

The event was first reported to the NIH Office of Animal Care and Use by the NIAID-RML ACUC Coordinator on April 25, 2022.

Please contact me or Dr. Stephen Denny, Director, Office of Animal Care and Use, if additional information or clarifications are required.

Richard G. Wyatt -S

Digitally signed by Richard G. Wyatt -S  
Date: 2022.06.13 09:54:45 -0400

Michael M. Gottesman, M.D.

Attachment

cc: Dr. Wyatt  
Dr. Hanley  
Dr. Denny



May 31, 2022

To: Michael Gottesman, M.D., NIH Deputy Director for Intramural Research

From: Laszlo Kari, M.D., Chair, RML Animal Care and Use Committee

Subject: RML Animal Incident Report

In accordance with Assurance D16-00602 and PHS Policy IV.F.3., the RML ACUC would like to provide this report of an incident that occurred involving the care and use of animals in biomedical research.

Summary of Incident:

During transfer of 8 cages of mice between buildings, a miscommunication occurred, resulting in valves not being installed properly into Hydropac pouches. The animals were infected the next day per an approved ASP. Per SOP and ASP, animal technicians and research group performed health checks daily. During the study, animals started to show clinical signs of disease consistent with either the study parameters or potential dehydration. On April 21, 2022 upon discovery of the valves not being installed, the animal technician immediately provided water/gel and notified a clinical veterinarian. One animal was euthanized at that time, all remaining animals were actively eating and drinking. Following discussions with the research group, the decision was made to euthanize all animals. The ACUC Coordinator notified OACU on April 25.

The RML ACUC reviewed the incident at a fully convened ACUC meeting held on April 28, 2022. The ACUC voted this was a reportable incident involving a condition that jeopardized the health and wellbeing of animals.

Corrective Actions:

To address this incident, the following corrective actions were taken:

- The SOP regarding animal transfer has been updated
- The SOP regarding rodent animal room and health checks has been updated
- Animal care staff has read and signed off on the updated SOPs
- Animal care staff has received documented training on proper water pouch placement
- The research group will include checks for food/water during health checks

The Committee feels these actions should reasonably ensure that additional issues of this nature will not occur in the future.

Thank you for your consideration of this matter.

Sincerely,

(b) (6)

Laszlo Kari, M.D.  
Chair, RML Animal Care and Use Committee

## **Wolff, Axel (NIH/OD) [E]**

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Thursday, June 16, 2022 6:45 AM  
**To:** Denny, Stephen (NIH/OD) [E]  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: D16-00602 NIH Animal Incident Report (RML 20-22))

Thank you for this report, Dr. Denny. We will send a response soon.  
Axel Wolff

**From:** Denny, Stephen (NIH/OD) [E] <stephen.denny@nih.gov>  
**Sent:** Wednesday, June 15, 2022 5:02 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Subject:** D16-00602 NIH Animal Incident Report (RML 20-22))

Dear OLAW/DCO,

The attached documents from the NIH Institutional Official and the NIH National Institute of Allergy and Infectious Diseases – Rocky Mountain Laboratories (RML) ACUC address an animal incident involving failure to correctly follow cage setup procedures per an ACUC-approved SOP. The event was first reported to the NIH Office of Animal Care and Use by the RML ACUC Coordinator on April 25, 2022.

If you have any questions please contact me via email or at the phone number listed below. Thank you, Steve

STEPHEN DENNY, DVM, MS, DACLAM, DACVPM | Director, Office of Animal Care and Use | NIH Bethesda Campus, Building 31/Room B1C37 |  
Phone: (301) 435-2188 | *NIH . . . Turning Discovery Into Health* |