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

EOR EXPRESS MAIL: Office of Laboratory Animal Welfare 6700B Rockledge Drive, Suite 2500 Bethesda, Maryland 20817 Telephone: (301) 496-7163 Facsimile: (301) 480-3387

DATE:	September	15,	2022

TO:	Nina F. Schor, M.D., Ph.D.
	Deputy Director for Intramural Research, NIH

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

SUBJECT: Animal Welfare Investigation (NCI #25-22) - Animal Welfare Assurance A4149-01 [Case 17C]

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your July 5, 2022 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the NIH Intramural Research Program. This letter had not been preceded by a preliminary report to OLAW.

According to the information provided, this Office understands that the National Cancer Institute 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 on May 4, 2022, 4 mice were provided doxycycline feed, which was not described in the approved protocol. It is stated a lab member who requested the feed was not aware that the doxycycline feed was not approved in the protocol.

In response, the feed was removed quickly, and the mice were euthanized. The veterinary staff reminded the laboratory the importance of following protocols directly and of the methods to amend protocols to include changes such as the addition of a specific feed. The matter was discussed at the ACUC meeting on June 8, 2022 and the corrective actions were approved.

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

Sincerely, Jacquelyn T. Tubbs -S

Digitally signed by Jacquelyn T. Tubbs -S Date: 2022.09.15 08:01:29 -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. Remy Bossulet

McCoy, Devora (NIH/OD) [E]

From:	McCoy, Devora (NIH/OD) [E]
Sent:	Thursday, September 15, 2022 12:55 PM
To:	Schor, Nina (NIH/OD) [E]
Cc:	OLAW Division of Compliance Oversight (NIH/OD); Denny, Stephen (NIH/OD) [E]; Wyatt,
	Richard G (NIH/OD) [E]; Bosselut, Remy (NIH/NCI) [E]
Subject:	OLAW Case A4149-17C
Attachments:	A4149-17C.pdf
Follow Up Flag: Flag Status:	Follow up Flagged

Good afternoon Dr. Schor,

Attached please find Dr. Tubbs' response to OLAW Case A4149-17C. If you have any questions, feel free to contact us by phone or by e-mail.

1

Best, Devora

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



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health Bethesda, Maryland 20892 www.nih.gov

A4149-17C

July 5, 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 (NCI 26-22)

This correspondence conveys the results of an animal incident investigation by the NIH National Cancer Institute (NCI) ACUC in accordance with Assurance D16-00602 and PHS Policy IV.F.3. The incident involved the unapproved feeding of doxycycline to mice. Four mice were euthanized due to this failure to follow the ACUC-approved animal study proposal.

The event was first reported to the NIH Office of Animal Care and Use by the NCI Acting Animal Program Director on May 4, 2022.

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

Michael M. Digitally signed by Michael M. Gottesman -S Date: 2022.07.05 16:26:51 October 16:26:51

Michael M. Gottesman, M.D.

Attachment

cc: Dr. Wyatt Dr. Bosselut Dr. Denny





Public Health Service

National Institutes of Health National Cancer Institute Bethesda, Maryland 20892

Laboratory of Immune Cell Biology Bldg. 37, Room 3016 Bethesda, Maryland 20892 Phone: 240 760-6866 Fax: 240 541-4483 E-Mail: bosselur@mail.nih.gov

Date: 6/29/2022

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

From: Rémy Bosselut, M.D., Ph.D ACUC Chair, NCI

Subject: Reportable Animal Incident: Inappropriate animal feed

On May 4, 2022, four mice assigned to a single approved ACUC protocol were provided doxycycline feed. This feed was not described in the ACUC-approved protocol and was identified shortly after placement in the cage by the facility veterinary and technical staff who reported this incident to the lab and the NCI veterinary staff. The laboratory staff indicated a miscommunication between two members resulted in the error: the member who had requested the feed was not aware that the doxycycline feed was not approved in the protocol. The laboratory removed the feed quickly and the mice were euthanized despite not showing any adverse clinical effects.

Since the feed was not approved in an ACUC protocol, we reported this incident to the Office of Animal Care and Use (OACU) and the OACU subsequently reported the incident to the Office of Laboratory Animal Welfare (OLAW).

This was the first such instance for this group. They expressed apologies for the mistake and the veterinary staff reminded the laboratory of the necessity to follow ASPs directly and of the methods to amend protocols to include changes such as the addition of this feed. This issue was discussed at the NCI ACUC meeting on June 8, 2022. The committee approved the corrective measure.

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

(b) (6)

Sincerely,

Rémy Bosselut, M.D., Ph.D Chair, NCI ACUC

Cc: Tom Misteli , Ph.D. Glenn Merlino, Ph.D. Joshua Kramer, D.V.M., M.S.

McCoy, Devora (NIH/OD) [E]

From:	OLAW Division of Compliance Oversight (NIH/OD)
Sent:	Wednesday, August 10, 2022 12:49 PM
То:	Denny, Stephen (NIH/OD) [E]
Cc:	OLAW Division of Compliance Oversight (NIH/OD)
Subject:	RE: D16-00602 NIH Animal Incident Report (NCI 26-22))

Good afternoon Dr. Denny,

Thank you for sending us this report and we will send an official response soon.

Best, Devora

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

From: Denny, Stephen (NIH/OD) [E] <stephen.denny@nih.gov> Sent: Wednesday, August 10, 2022 11:12 AM To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov> Subject: D16-00602 NIH Animal Incident Report (NCI 26-22))

Dear OLAW/DCO,

The attached documents from the NIH Institutional Official and the NIH National Cancer Institute (NCI) ACUC address an animal incident involving mice. The event was first reported to the NIH Office of Animal Care and Use by the NCI Acting Attending Veterinarian on May 4, 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** |

1