



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) 480-3387

June 30, 2022

Re: Animal Welfare Assurance
A3224-01 [OLAW Case 1R]

Dr. Erin Kobetz
Vice Provost for Research
University of Miami
1400 NW 10th Ave -
(b) (4) Dominion Towers
Miami, FL 33136

Dear Dr. Kobetz,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your letter (received June 10, 2022 via email correspondence) reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of Miami Miller School of Medicine. This letter had not been preceded by a preliminary report to OLAW.

According to the information provided, this Office understands that the University of Miami Miller School of Medicine Animal Care and Use Committee (ACUC) determined that instances of noncompliance occurred with respect to: use of an improper and unapproved method of euthanasia on an animal. The final report states the IACUC determined a mouse was euthanized by a method that compromised the welfare of the animal, which was also not an approved or proper method of euthanasia. The Principal Investigator (PI) determined a staff member was responsible for the incident and the individual ceased animal work, pending the outcome of an investigation.

Per the report, the IACUC voted to have the entire lab undergo additional training on euthanasia techniques. The PI and the staff member were mandated to meet separately with the Director of Compliance and the IACUC Chair to discuss the seriousness of this event and the importance of using appropriate techniques. They were informed that any future protocol or policy violations may result in serious consequences.

In response to the incident, the PI and the entire research team must perform self-PAMs (post-approval monitoring), which means the team must review the research to verify that it fully complies with the protocols and that no policies have been violated. It is understood that following completion of training and the mandated meeting, the staff member was permitted to resume work with animals. It is also understood that self-PAMs are ongoing.

It is noted that this research is supported by NIH funding. Based on its assessment of this explanation, OLAW understands that the University of Miami Miller School of Medicine 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. Kobetz
June 30, 2022
OLAW Case A3224-IR

Sincerely,

Jacquelyn

T. Tubbs -S

Digitally signed by Jacquelyn T.
Tubbs -S
Date: 2022.06.30 15:31:38 -04'00'

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

cc: IACUC Contact

McCoy, Devora (NIH/OD) [E]

From: McCoy, Devora (NIH/OD) [E]
Sent: Thursday, June 30, 2022 4:46 PM
To: ekobetz@med.miami.edu
Cc: OLAW Division of Compliance Oversight (NIH/OD); (b) (6)
Subject: OLAW Case A3224-1R
Attachments: SIGNED Compliance Case University of Miami Miller School of Medicine 1R.pdf

Good afternoon Dr. Kobetz,

Attached please find Dr. Tubbs' final response to OLAW Case A3224-1R. 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



OFFICE OF THE VICE PROVOST FOR
RESEARCH & SCHOLARSHIP

A3224-1R

Dr. Axel Wolff, Deputy Director
Office of Laboratory Animal Welfare
Rockledge One, Suite 2500
6700B Rockledge Drive – MSC 6910
Bethesda, MD 20892-7982

Re: NIH project R01DA047157
Assurance number: A3224-01

Dear Dr. Wolff,

I am writing to inform the OLAW of a serious noncompliance in an animal research program at the University of Miami Miller School Of Medicine.

During a semi-annual inspection, the IACUC determined that a mouse had been euthanized using an improper and unapproved method that compromised the welfare of the animal. The PI responded immediately to the IACUC that he had determined this had been done by a staff member.

The PI agreed to have the staff member immediately stop working with animals pending the outcome of an investigation by the IACUC.

The IACUC discussed this issue at length and voted to have the entire lab undergo additional training on euthanasia techniques. In addition, the PI and the staff member were mandated to meet individually with the Director of Compliance and the IACUC Chair to discuss the seriousness of this event and the importance of using appropriate techniques. During those meetings, both the PI and staff member were very cooperative and appeared to understand the gravity of what had been done. Further, they are aware that any future violations of protocol or policy could result in extremely serious consequences for this research program.

In addition, the PI and entire research team must conduct self-PAMs (post approval monitoring) on all of their protocols each month for 6 months after their training had been completed and reports detailing the outcomes must be reported to the IACUC each month. What this means is that the entire team must review the research to ensure that it fully complies with the protocols and that no policies have been violated. In the past, we have found that this method of having labs conduct PAMs of their own work has greatly enhanced their understanding of what is approved and thus has increased compliance in labs that have done this.

Following completion of training and meeting with the Director of Compliance and the IACUC Chair, the staff member has been allowed to resume working with animals. The PI understands the seriousness of this event and has promised to exert greater oversight over everything happening in the lab to prevent future noncompliance. The self-PAMs are ongoing.



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I agree with the recommendations of the IACUC, and I have taken steps to see that they are implemented going forward. I consider the issue resolved and closed. At the University of Miami, we strive to take excellent care of our animals and we are confident that no additional noncompliance will occur with this research team.

Sincerely,

(b) (6)

Erin Kobetz, PhD, MPH
Vice Provost for Research and Scholarship
Associate Director, Population Sciences and Cancer Disparity,
Sylvester Comprehensive Cancer Center
Professor, Medicine and Public Health Sciences

cc:

(b) (6)

Dr. Sari Izenwasser, IACUC Chair

Wolff, Axel (NIH/OD) [E]

From: Wolff, Axel (NIH/OD) [E]
Sent: Monday, June 13, 2022 8:42 AM
To: Izenwasser, Sari
Subject: RE: Noncompliance report

Thank you for this report, Dr. Izenwasser. We will send a response shortly. In future, please submit all final reports to olawdco@od.nih.gov so that OLAW staff can process them even when I am not available.
Axel Wolff

From: Izenwasser, Sari <sizenwasser@med.miami.edu>
Sent: Friday, June 10, 2022 5:32 PM
To: Wolff, Axel (NIH/OD) [E] <wolffa@od.nih.gov>
Cc: Kobetz, Erin <ekobetz@med.miami.edu>; (b) (6)
(b) (6)
Subject: [EXTERNAL] Noncompliance report

Dear Dr. Wolff

Attached please find a letter from the University of Miami reporting noncompliance on an NIH-funded project. Please let us know if you have any questions.

Best,

Sari

Sari Izenwasser, Ph.D.
Professor
Department of Psychiatry & Behavioral Sciences
University of Miami Miller School of Medicine
Miami, FL 33136
(b) (6)

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