



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

July 6, 2022

Re: Animal Welfare Assurance
#A3343-01 (OLAW Case 3E)

Dr. Giulio Draetta
Chief Scientific Officer
University of Texas MD Anderson Center
1515 Halcombe Boulevard – (b) (4)
Houston, Texas 77030

Dear Dr. Draetta,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your June 24, 2022, letter reporting a series of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the MD Anderson Cancer Center. According to the information provided, OLAW understands that fifteen cages of mice were held at an unapproved satellite laboratory and for a minimum of five days. Daily health checks were not performed, and several cages lacked identifying cage cards and water for an undetermined period. Three mice died of dehydration as a result of the identified noncompliance.

The corrective actions consisted of the Principal Investigator and all animal users taking the “*Working with the IACUC*” training module and conducting all future animal research activities exclusively within the vivarium. During a recent post-approval monitoring (PAM) visit, the IACUC Chair, Department of Veterinary Medicine and Surgery Chair and PAM monitor reviewed all laboratory animal procedures, as well as potential implications of further noncompliance, and retrained all personnel on the requirements for complying with approved animal protocols and IACUC polices. The PI must provide a written action plan to the IACUC on ensuring compliance with approved protocols and IACUC polices. In addition, all the PI’s animal care and use protocols have been placed on a one-year probation with imposed escalating sanctions, including suspension of animal use privileges, for any future noncompliance. Federal charges for expenses incurred during the period of noncompliance have been excluded from the applicable NIH grant and the relevant funding agency has been notified of the incident.

The establishment and application of policies and practices that are consistent with the provisions of the PHS Policy on Humane care and Use of Laboratory Animals at the MD Anderson Cancer Center are commendable and avoid the perception of a double standard. We appreciate having been informed about this matter and find no cause for further action by this Office.

Sincerely,

Neera V.

Gopee -S

Neera V. Gopee, DVM, PhD, DAACLAM, DABT
Associate Director, Animal Welfare Policy
Office of Laboratory Animal Welfare
National Institutes of Health

Digitally signed by Neera V.
Gopee -S
Date: 2022.07.06 11:50:45
-04'00'

cc: IACUC Chair

June 24, 2022

VIA ELECTRONIC SUBMISSION
olawdco@mail.nih.gov

Brent C. Morse, DVM, DACLAM
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
Rockledge 1, Suite 360, MSC 7982
6705 Rockledge Drive
Bethesda, MD 20892-7982

Re: Reportable Incident; Animal Assurance # A3343-01
MDA internal reference # HLY3-0322-001
Funding: NIH 1R01CA218036-01 (FP00000060)
NIH 1R01CA231011-01A1 (FP00003585)

Dear Dr. Morse,

On March 8, 2022, 15 cages of mice were discovered in a research laboratory not approved for animal housing. It was further determined that the cages of mice had been held in the laboratory for at least 5 days in violation of Institutional Animal Care and Use Policy 3.21, Experimental Rodents in Laboratory Spaces. Several of the cages did not have identifying cage cards and were without water for an undetermined amount of time. Three mice were dead.

A report of failure to adhere to approved IACUC protocol.

On March 8, 2022, 15 cages of live mice were kept in a research laboratory not approved for animal housing for at least 5 days. Daily health checks were not conducted, and three mice were dead. Several of these cages did not have identifying cage cards and were without water for an undetermined amount of time.

The IACUC was extremely concerned about the gravity of this event and required the following corrective actions.

1. The Principal Investigator (PI) and all animal manipulators will take *Working with the IACUC* training module in American Association for Laboratory Animal Science Learning Library.
2. A Post Approval Monitoring (PAM) visit occurred May 16, 2022 with the PI and all laboratory personnel. The IACUC Chair, the Department of Veterinary Medicine and Surgery (DVMS) Chair, and the PAM representative reviewed all laboratory animal procedures and retrained all personnel on the requirements to adhere to approved animal protocols and IACUC policies. The potential consequences of further noncompliance were also reviewed.
3. The PI will provide a written report to the IACUC detailing how he will ensure compliance to all animal use protocols and IACUC policies going forward.
4. All animal research activities for the laboratory will be required to be conducted solely in the vivarium.

5. All animal care and use protocols for the PI have been placed on probation for one year wherein any further noncompliant events will result in more severe corrective actions including the potential for suspension of animal use privileges.

The IACUC reviewed the incident and the corrective and preventive action at its fully convened meeting on April 19, 2022 and agreed that the corrective and preventive actions were sufficient to prevent any future recurrence of the above-listed non-compliance with the PHS Policy.

The costs associated with the maintenance and care of the animals during the period of noncompliance that were initially charged to NIH grant 1R01CA218036-01 and 1R01CA231011-01A1 have been removed from such grant. The NIH funding component has been notified.

MD Anderson is committed to assuring compliance with the PHS policy and the Guide, and to maintaining proper measures and procedures to ensure the appropriate care and use of all animals involved in research. I will be happy to respond to any additional questions you may have regarding this report.

Regards,

(b) (6)

Giulio Draetta, M.D., Ph.D.
Chief Scientific Officer
MD Anderson Cancer Center
1515 Holcombe Blvd.

(b) (4)
Houston, TX 77030

(b) (6)

cc: Patrick Dougherty, Ph.D., IACUC Chair

(b) (6)

McCoy, Devora (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, June 27, 2022 7:55 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: MD Anderson Cancer Center (A3343-01)

Good morning (b) (6)

Thank you for sending these reports. We will review them and send a 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: (b) (6)
Sent: Friday, June 24, 2022 6:19 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Dougherty,Patrick <pdougherty@mdanderson.org>; (b) (6)
(b) (6) Draetta,Giulio <GDraetta@mdanderson.org>
Subject: [EXTERNAL] MD Anderson Cancer Center (A3343-01)

Dear Dr. Morse,

Please find attached our final reports for incidents that occurred at MD Anderson Cancer Center (A3343-01). Please contact me if you have any questions.

Thank you,

(b) (6)

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