



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 3G)

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 two instances 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 twenty-four mice were administered an unapproved agent using unapproved subcutaneous osmotic pump implants which resulted in the demise of sixteen animals and euthanasia of six moribund mice. In addition, five moribund or deceased mice were found unattended in a vivarium procedure room during the March AAALAC site visit.

The corrective actions consisted of the Principal Investigator and animal users meeting with the Post Approval Monitor and a veterinarian to review the IACUC protocol and be retrained on IACUC Standard Operating Procedures 3.16 *Rodent Surgery* and 3.10 *Euthanasia and Death endpoints*, as well as cage card procedures. The relevant funding agency has been notified and all federal charges for expenses incurred during the period of noncompliance have been excluded from the applicable NIH grant.

Based on the information provided, OLAW is satisfied that appropriate actions have been taken to investigate, correct and prevent recurrence of the noncompliance. We appreciate being informed of these matters and find no cause for action by this Office.

Sincerely,

Neera V. Gopee -S

Digitally signed by Neera V.  
Gopee -S  
Date: 2022.07.06 15:06:05 -04'00'

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

cc: IACUC Chair

June 24, 2022

**VIA ELECTRONIC SUBMISSION**

[olawdco@mail.nih.gov](mailto: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 # HGD3-0322-001  
Funding: NCI 5P50CA221707-03 (FP00001122\_RES1) and 5R01CA218139-05 (FP00002097)

Dear Dr. Morse,

I am writing to provide a report of The University of Texas MD Anderson Cancer Center Institutional Care and Use Committee's (IACUC) finding of serious noncompliance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy). A full explanation of the circumstances of this serious non-compliance as well as actions taken and planned is provided below.

**A report of failure to adhere to approved IACUC protocol.**

On March 8 and 9, 2022, 16 out of 24 mice were found dead and an additional 6 were euthanized due to moribund state following an unapproved subcutaneous implant of osmotic pumps delivering an unapproved agent. Additionally, during the March 2022 AAALAC site visit, five associated cages containing five mice were found either dead or in moribund state unattended in a vivarium procedure room.

The Principal Investigator (PI) and animal manipulators will met with the Post Approval Monitor and a Veterinarian on June 1, 2022 to review their IACUC protocol and to be retrained on IACUC Standard Operating Procedures (SOPs) 3.16 *Rodent Surgery* and 3.10 *Euthanasia and Death Endpoints*, and cage card procedures.

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 NCI grants 5P50CA221707-03 and 5R01CA218139-05 have been removed from such grant. The NCI 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]**

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**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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