



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 3F)

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 an instance 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 during a recent AAALAC site visit, the Principal Investigator (PI) and research personnel described the non-sterile preparation and unapproved administration of urethane to anesthetized mice while performing previous non-survival surgeries on a PHS-supported study.

The corrective actions consisted of the PI and research personnel immediately halting the use of urethane and consulting with a veterinarian on an appropriate pharmaceutical grade anesthetic for their studies. In addition, the PI and animal users met with the Post Approval Monitor and IACUC Veterinarian to review the IACUC protocol, IACUC SOP 3.02 *Anesthesia/Analgesia*, and the use of anesthetics for their specific studies.

Based on the information provided, OLAW is satisfied that appropriate actions have been taken to investigate, correct and prevent recurrence of the noncompliance. Your prompt and thorough resolution of this matter is commendable and consistent with the PHS Policy philosophy of monitored self-regulation. We appreciate having been informed of this matter and find no cause for further action by this Office.

Sincerely,

Neera V.

Gopee -S

Neera V. Gopee, DVM, PhD, DACLAM, 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 13:03:05
-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 # HDG4-0322-001
Funding: NCI 5R01CA208535-04 (FP00002216)

Dear Dr. Morse,

I am writing to provide a report of a finding by The University of Texas MD Anderson Cancer Center Institutional Care and Use Committee (IACUC) of 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 non-compliance event as well as corrective actions taken and planned is provided below.

A report of failure to adhere to approved IACUC protocol.

On March 8, 2022, animal manipulators described the unapproved use and non-sterile preparation of urethane to anesthetize mice during previous non-survival surgeries to a group of AAALAC site visitors. The Principal Investigator (PI) and research staff immediately ceased the use of urethane and contacted a veterinarian to discuss an appropriate pharmaceutical grade anesthetic for their experiments.

The PI and animal manipulators met with the Post Approval Monitor and IACUC Veterinarian on May 20, 2022 to review their IACUC protocol, IACUC SOP 3.02 *Anesthesia/Analgesia*, and the use of anesthetics for their specific experiments.

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

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)

The information contained in this e-mail message may be privileged, confidential, and/or protected from disclosure. This e-mail message may contain protected health information (PHI); further dissemination of PHI should comply with applicable federal and state laws. If you are not the intended recipient, or an authorized representative of the intended recipient, any further review, disclosure, use, dissemination, distribution, or

copying of this e-mail message or any attachment (or the information contained therein) is strictly prohibited. If you think that you have received this e-mail message in error, please notify the sender by return e-mail and delete all references to it and its contents from your systems.

The information contained in this e-mail message may be privileged, confidential, and/or protected from disclosure. This e-mail message may contain protected health information (PHI); dissemination of PHI should comply with applicable federal and state laws. If you are not the intended recipient, or an authorized representative of the intended recipient, any further review, disclosure, use, dissemination, distribution, or copying of this message or any attachment (or the information contained therein) is strictly prohibited. If you think that you have received this e-mail message in error, please notify the sender by return e-mail and delete all references to it and its contents from your systems.

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and are confident the content is safe.