



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

January 28, 2022

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

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 letter dated January 14, 2022 reporting a noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of Texas MD Anderson Cancer Center. According to the information provided, OLAW understands that on October 30, 2021, ten cages containing 50 adult mice with wound clips were found without post-operative monitoring cards. The animals were active, in good body condition, and not apparently in pain or distress on veterinary assessment. A reminder email was sent to the lab regarding the post-operative monitoring card requirement. Subsequently, it was determined that no analgesics had been given to the mice that underwent subcutaneous tumor implantations the previous week. The associated activity was PHS-funded. The costs associated with the maintenance and care of the animals during the period of noncompliance that were initially charged to the grant have been removed. The NIH funding component has been notified.

The following corrective and preventive actions were implemented by the IACUC:

1. The PI will counsel all animal manipulators on the requirement to provide analgesics at the time of surgery and post-operatively according to the approved protocol.
2. The PI will remind all animal manipulators to review applicable sections of the protocol prior to initiating animal experiments.
3. The PI and all animal manipulators will take "*Aseptic Technique for Rodent Survival Surgery*" and "*Working with the IACUC*" training modules in American Association for Laboratory Animal Science Learning Library.
4. IACUC Post-Approval Monitors visited the lab to review and refresh training on the protocol, surgical records including post-operative cage cards, IACUC SOP *Rodent Survival Surgery*, and approved analgesics.

The prompt consideration of this difficult matter by the University of Texas MD Anderson Cancer Center was consistent with the philosophy of institutional self-regulation. Similarly, the actions taken to resolve the issue and prevent recurrence were appropriate. We appreciate being informed of this matter and find no cause for further action by this office.

*Page 2 – Dr. Draetta
January 28, 2022
OLAW Case A3343-3D*

Sincerely,

Brent C. Morse -S

Digitally signed by Brent C.
Morse -S
Date: 2022.01.28 17:02:48 -05'00'

Brent C. Morse, DVM
Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC contact

January 14, 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 # HHM3-1122-001
Funding: NIH 7U24 CA220325-03 (FP00011842)

Dear Dr. Morse,

I am writing to provide a report a finding by the University of Texas MD Anderson Cancer Center Institutional Care and Use Committee (IACUC) of serious noncompliance with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals. 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 IACUC-approved protocol.

On October 30, 2021, Department of Veterinary Medicine and Surgery (DVMS) staff observed ten cages containing 50 adult mice with wound clips without post-operative monitoring cards on the cages. The animals were active, in good body condition, and not apparently in pain or distress on veterinary assessment. A reminder email was sent to the lab regarding the post-operative monitoring card requirement. In subsequent email communication on November 1, 2021 between the clinical veterinarian and Principal Investigator (PI), it was determined that no analgesics had in fact been given to the 50 mice that underwent subcutaneous tumor implantations the previous week. A follow up veterinary assessment of the animals was performed on November 2, 2021 and found the mice were active and not apparently in pain or distress.

The IACUC reviewed the incident at its fully convened meeting on November 16, 2021 and agreed to require the following corrective and preventive actions.

1. The PI will counsel all animal manipulators on the requirement to provide analgesics at the time of surgery and post-operatively according to the approved protocol.
2. The PI will remind all animal manipulators to review applicable sections of the protocol prior to initiating animal experiments.
3. The PI and all animal manipulators will take "Aseptic Technique for Rodent Survival Surgery" and "Working with the IACUC" training modules in American Association for Laboratory Animal Science Learning Library.
4. IACUC Post Approval Monitors visited the lab on November 30, 2021 to review and refresh training on the protocol, surgical records including post-operative cage cards, IACUC SOP 3.16 *Rodent Survival Surgery*, and approved analgesics.

5. The PI will provide a written response to the IACUC detailing how the required corrective actions were implemented.

The IACUC agreed that the corrective and preventive actions listed above were sufficient to prevent any future recurrence of the above-listed non-compliance with 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 7U24 CA220325-03 have been reversed and charged to a non-PHS resource. 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.
Sr. Vice President, 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)

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, January 19, 2022 7:05 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: MD Anderson Cancer Center (A3343-01) HHM3-1122-001

Thank you for this report. We will send a response soon.

Axel Wolff, M.S., D.V.M.
Deputy Director, OLAW

From: (b) (6)
Sent: Friday, January 14, 2022 10:49 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Dougherty, Patrick <pdougherty@mdanderson.org>; (b) (6)
Subject: [EXTERNAL] MD Anderson Cancer Center (A3343-01) HHM3-1122-001

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.

Please find attached our final report for an incident 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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