



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 3B)

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 an adverse event within the animal care and use program at the University of Texas MD Anderson Cancer Center. According to the information provided, OLAW understands that on December 2, 2021, an animal manipulator was found transporting four cages containing a total of 20 mice in a method that failed to adhere to institution standards. This was corrected on the spot, but it was subsequently discovered that transport of animals outside of the vivarium to perform euthanasia in the laboratory was not a protocol-approved activity. The associated activity is 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 restored and charged to a non-PHS resource. The NIH funding component has been notified.

As corrective and preventive actions, the PI and all animal manipulators will re-take *Working with the IACUC* training module in the American Association for Laboratory Animal Science Learning Library. Additionally, Post-Approval Monitors will visit the lab to review approved protocol activities and provide refresher training to the PI and animal manipulators on proper transportation methods.

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.

Sincerely,

**Brent C. Morse -S**

Digitally signed by Brent C.  
Morse -S  
Date: 2022.01.28 17:00:56 -05'00'

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

cc: IACUC contact

**Morse, Brent (NIH/OD) [E]**

---

**From:** Morse, Brent (NIH/OD) [E]  
**Sent:** Monday, January 31, 2022 11:12 AM  
**To:** Durkin, Kimberly (NIH/NCI) [E]  
**Cc:** Wolff, Axel (NIH/OD) [E]  
**Subject:** OLAW Case re: 5R01CA214954-04  
**Attachments:** Draetta MDAC 3343-3B.pdf

Hello Ms. Durkin,

Attached is OLAW's final determination regarding our case involving the above grant. We found MD Anderson's corrective actions to be appropriate and have closed the case. If you have any questions, please reference OLAW Case # A3343-3B in your email.

Best regards, Brent Morse

Brent C. Morse, DVM, DACLAM  
Director, Division of Compliance Oversight  
Office of Laboratory Animal Welfare  
National Institutes of Health

**Wolff, Axel (NIH/OD) [E]**

A3343-3B

**From:** Durkin, Kimberly (NIH/NCI) [E]  
**Sent:** Tuesday, January 25, 2022 6:30 AM  
**To:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: Reporting Noncompliance with Terms and Conditions 5R01CA214954-04

**Follow Up Flag:** Follow up  
**Flag Status:** Flagged

Hi Axel,

Thank you for researching this request. I am assuming they didn't report until I notified them that they had to report to OLAW. Glad they followed the guidance and you received the information from the recipient.

Best,  
Kim

*Kimberly Durkin*  
Supervisory Team Leader  
Office of Grants Administration  
NIH/NCI  
Phone: 240.276.5178  
Email: [kimberly.durkin@nih.gov](mailto:kimberly.durkin@nih.gov)

**From:** OLAW Division of Compliance Oversight (NIH/OD) <[olawdco@od.nih.gov](mailto:olawdco@od.nih.gov)>  
**Sent:** Tuesday, January 25, 2022 5:46 AM  
**To:** Durkin, Kimberly (NIH/NCI) [E] <[kimberly.durkin@nih.gov](mailto:kimberly.durkin@nih.gov)>  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD) <[olawdco@od.nih.gov](mailto:olawdco@od.nih.gov)>  
**Subject:** RE: Reporting Noncompliance with Terms and Conditions 5R01CA214954-04

Hello Mr. Durkin,

Unusual for your type of inquiry, the letter to OLAW did not arrive until *after* your notification to this Office. Most grants inquiries arrive weeks or months after the case has closed at OLAW. At this point in time, a notification has been filed with OLAW by MD Anderson but it needs to be 1) in-processed ; 2) assigned to a veterinary reviewer; 3) assessed for appropriate corrective/preventive measures ; 4) reply letter written; 5) final assessment and closeout if acceptable. This will take several weeks at least. Your request is in the case file and you will be copied on the entire file upon completion. As the grantee has removed unauthorized animal charges from the grant, there is nothing you need to do at this time. OLAW will be handling the matter at this time and will close the loop with you soon as completed.

Axel Wolff

**From:** Durkin, Kimberly (NIH/NCI) [E] <[kimberly.durkin@nih.gov](mailto:kimberly.durkin@nih.gov)>  
**Sent:** Monday, January 24, 2022 7:06 AM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <[olawdco@od.nih.gov](mailto:olawdco@od.nih.gov)>  
**Subject:** RE: Reporting Noncompliance with Terms and Conditions 5R01CA214954-04

Hello Axel,

Are there any status updates from my email below?

Best,  
Kim

*Kimberly Durkin*  
Supervisory Team Leader  
Office of Grants Administration  
NIH/NCI  
Phone: 240.276.5178  
Email: [kimberly.durkin@nih.gov](mailto:kimberly.durkin@nih.gov)

**From:** OLAW Division of Compliance Oversight (NIH/OD) <[olawdco@od.nih.gov](mailto:olawdco@od.nih.gov)>  
**Sent:** Friday, January 14, 2022 8:12 AM  
**To:** Durkin, Kimberly (NIH/NCI) [E] <[kimberly.durkin@nih.gov](mailto:kimberly.durkin@nih.gov)>  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD) <[olawdco@od.nih.gov](mailto:olawdco@od.nih.gov)>  
**Subject:** FW: Reporting Noncompliance with Terms and Conditions 5R01CA214954-04

Hello Ms. Durkin,

We will look for this case and get back to you sometime next week.

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

**From:** Durkin, Kimberly (NIH/NCI) [E] <[kimberly.durkin@nih.gov](mailto:kimberly.durkin@nih.gov)>  
**Sent:** Thursday, January 13, 2022 12:10 PM  
**To:** OLAW Division of Assurances (NIH/OD) <[olawdoa@od.nih.gov](mailto:olawdoa@od.nih.gov)>  
**Cc:** Perloff, Marjorie (NIH/NCI) [E] <[perloffm@mail.nih.gov](mailto:perloffm@mail.nih.gov)>  
**Subject:** FW: Reporting Noncompliance with Terms and Conditions 5R01CA214954-04

Hello OLAW,

We received a reporting of noncompliance from MD Anderson for NCI Award: 5R01CA214954-04. I understand the recipient is supposed to report certain situations to OLAW per [NOT-OD-05-034](#). I wanted to follow-up to determine if they have reported this issue to you and if there is any additional action we need to take for this award.

Please let us know if you have any questions or need additional information to assist with your review.

Best,  
Kim

*Kimberly Durkin*

Supervisory Team Leader  
Office of Grants Administration  
NIH/NCI  
Phone: 240.276.5178  
Email: [kimberly.durkin@nih.gov](mailto:kimberly.durkin@nih.gov)

**From:** (b) (6)  
**Date:** Monday, January 10, 2022 at 10:47:01 AM  
**To:** "Reis, Romy (NIH/NINDS) [E]" <[mondesir@mail.nih.gov](mailto:mondesir@mail.nih.gov)>, "Perloff, Marjorie (NIH/NCI) [E]" <[perloffm@mail.nih.gov](mailto:perloffm@mail.nih.gov)>  
**Cc:** (b) (6)  
**Subject:** [EXTERNAL] Reporting Noncompliance with Terms and Conditions 5R01CA214954-04

**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.

Good morning Romy and Marjorie,

I am notifying you of noncompliance with the terms and conditions of the federal award NCI 5R01CA214954-04 (FP00002821) (AWD00001326) awarded to Xiangwei Wu. Specifically, an animal manipulator in Dr. Wu's lab failed to adhere to the IACUC -approved protocol funded by this award. The department has completed non-salary cost transfers that removed the charges from the federal grant to a non-grant fund.

Please let me know if you need any additional information.

Thanks,

(b) (6)

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January 14, 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 # HXW3-1222-001  
Funding: NCI 5R01CA214954-01A1 (FP00002821)

Dear Dr. Morse,

I am writing to report a finding by the University of Texas MD Anderson Cancer Center (MD Anderson) 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 finding as well as corrective actions taken and planned is provided below.

**Failure to adhere to IACUC SOP and approved protocol activities.**

On December 2, 2021, Department of Veterinary Medicine and Surgery (DVMS) personnel observed an animal manipulator stacking 4 cages containing a total of 20 mice onto a cart nested without bonnets or wire lids between the cages thus preventing access to food, water and proper ventilation. This method of transport failed to adhere to IACUC Standard Operating Procedure (SOP) 3.21 *Experimental Rodents in Laboratory Spaces*. The manipulator restored proper cage configuration upon intervention by the DVMS Associate Director and then transported the cages to their lab to perform euthanasia. It was subsequently discovered upon review of the associated IACUC protocol that transport of animals outside of the vivarium to perform euthanasia in the laboratory was not an approved activity.

The IACUC Chair met with the Principal Investigator (PI) and DVMS Associate Director to discuss the incident and the matter was further reviewed by the IACUC Executive Committee. It was determined that as corrective action the PI and all animal manipulators will re-take *Working with the IACUC* training module in the American Association for Laboratory Animal Science Learning Library (AALAS). Additionally, Post Approval Monitors will visit the lab on January 10, 2022 to review approved protocol activities and provide refresher training to the PI and animal manipulators on proper transportation methods as detailed in IACUC SOP 3.21 *Experimental Rodents in Laboratory Spaces*.

The IACUC reviewed the incident at its fully convened meeting on December 21, 2021 and agreed that the corrective action plan should be 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 NCI grant 5R01CA214954-01A1 have been restored 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 7:07 AM  
**To:** (b) (6)  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: MD Anderson Cancer Center (A3343-01) HXW3-1222-001

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) HXW3-1222-001

**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)

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.



**Wolff, Axel (NIH/OD) [E]**

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**From:** Durkin, Kimberly (NIH/NCI) [E]  
**Sent:** Friday, January 14, 2022 8:52 AM  
**To:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: Reporting Noncompliance with Terms and Conditions 5R01CA214954-04

**Follow Up Flag:** Follow up  
**Flag Status:** Flagged

Thank you.

--kim

**From:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Sent:** Friday, January 14, 2022 8:12 AM  
**To:** Durkin, Kimberly (NIH/NCI) [E] <kimberly.durkin@nih.gov>  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Subject:** FW: Reporting Noncompliance with Terms and Conditions 5R01CA214954-04

Hello Ms. Durkin,

We will look for this case and get back to you sometime next week.

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

**From:** Durkin, Kimberly (NIH/NCI) [E] <[kimberly.durkin@nih.gov](mailto:kimberly.durkin@nih.gov)>  
**Sent:** Thursday, January 13, 2022 12:10 PM  
**To:** OLAW Division of Assurances (NIH/OD) <[olawdoa@od.nih.gov](mailto:olawdoa@od.nih.gov)>  
**Cc:** Perloff, Marjorie (NIH/NCI) [E] <[perloffm@mail.nih.gov](mailto:perloffm@mail.nih.gov)>  
**Subject:** FW: Reporting Noncompliance with Terms and Conditions 5R01CA214954-04

Hello OLAW,

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Please let us know if you have any questions or need additional information to assist with your review.

Best,  
Kim

Kimberly Durkin  
Supervisory Team Leader  
Office of Grants Administration  
NIH/NCI  
Phone: 240.276.5178  
Email: [kimberly.durkin@nih.gov](mailto:kimberly.durkin@nih.gov)

**From:** (b) (6)  
**Date:** Monday, January 10, 2022 at 10:47:01 AM  
**To:** "Reis, Romy (NIH/NINDS) [E]" <[mondesir@mail.nih.gov](mailto:mondesir@mail.nih.gov)>, "Perloff, Mariorie (NIH/NCI) [F]" <[perloffm@mail.nih.gov](mailto:perloffm@mail.nih.gov)>  
**Cc:** (b) (6)  
**Subject:** [EXTERNAL] Reporting Noncompliance with Terms and Conditions 5R01CA214954-04

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Please let me know if you need any additional information.

Thanks,

(b) (6)

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