



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) 402-7065

May 2, 2019

Re: Animal Welfare Assurance  
#A3343-01 (OLAW Case 2Q)

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 April 24, 2019 reporting an instance of 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 February 22, 2019 two non-human primates developed skin lesions at injection sites after receiving daily subcutaneous administrations of a drug study vehicle possibly due to the pH. Medical treatment was initiated and the lesions were almost completely healed after four weeks of treatment. The protocol to which the animals were assigned is supported by PHS funds.

Corrective and preventive actions included implementing verification of the pH for every batch of the study drug vehicle.

The prompt consideration of this 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,

(b) (6)

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

cc: IACUC contact

Dr. Robert M. Gibbens, USDA, APHIS, AC

April 24, 2019

**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 # HJS8-0319-001  
Funding: NIH 5R33AI116208-05

Dear Dr. Morse,

As Institutional Official for The University of Texas MD Anderson Cancer Center (MD Anderson), it is my duty to report to you a finding of a serious deviation from the provisions of the *Guide for the Care and Use of Laboratory Animals* (Guide).

**Conditions that jeopardize the health or well-being of animals**

On February 22, 2019, two non-human primates developed skin lesions at injection sites after receiving daily subcutaneous administrations of a drug study vehicle possibly due to the pH. Medical treatment was initiated and the lesions were almost completely healed after 4 weeks of treatment.

The Principal Investigator and study staff immediately implemented verification of the pH for every batch of the study drug vehicle.

MD Anderson's Institutional Animal Care and Use Committee (IACUC) reviewed the incident and corrective and preventive actions at its fully convened meeting on April 16, 2019. The IACUC determined that the corrective and preventive actions were sufficient to prevent any future recurrence of this matter. The IACUC also determined that the matter did not have any effect on the PHS-supported animal research activity.

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.

Sincerely,

(b) (6)

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

(b) (4)

Houston, TX 77030  
(713) 792-6370

cc: Jim Bankson, Ph.D., IACUC Chair  
Madhu Purewal, Ph.D., J.D., Senior Legal Officer & Director, Institutional Compliance  
Gaylen Howell, Director, Office of Research Oversight and Integrity

(b) (6)

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

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Thursday, April 25, 2019 3:21 PM  
**To:** Howell, Gaylen W; OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: MD Anderson Incident Report # HJS8-0319-001 (A3343-01)

Thank you for providing this report Mr. Howell. We will send an official response soon.

Best regards, Brent Morse

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

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**From:** Howell, Gaylen W [mailto:gwhowell@mdanderson.org]  
**Sent:** Thursday, April 25, 2019 2:45 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Subject:** MD Anderson Incident Report # HJS8-0319-001 (A3343-01)

Dear Dr. Morse,

Please find attached our final report for an incident that occurred at MD Anderson Cancer Center. Please do not hesitate to contact me if you have any questions.

Thank you,

Gaylen Howell

Gaylen Howell, MA, MBA  
Director, Research Oversight & Integrity  
Office of Research Oversight & Integrity  
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THE UNIVERSITY OF TEXAS  
**MDAnderson Cancer Center**  
Making Cancer History®

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