



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

December 23, 2019

Re: Animal Welfare Assurance  
A3007-01 [OLAW Case 2J]

G. Michael Purdy, Ph.D.  
Executive Vice President for Research  
Columbia University Medical Center  
535 West 116<sup>th</sup> St. – (b) (4) Low Library MC 4310  
New York, NY 10027

Dear Dr. Purdy,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your December 16, 2019 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Columbia University following up on an initial August 9, 2019 notification by telephone.

According to the information provided, this Office understands that the Columbia University Animal Care and Use Committee (ACUC) determined that instances of noncompliance occurred with respect to: an individual conducting mouse survival surgery not in compliance with the applicable protocol. On July 31, 2019, an IACUC post-approval monitor notified the Executive Director of the IACUC, that an individual conducting mouse survival surgery was not in compliance with the approved protocol. The letter states that the research was supported by the Public Health Service under NIH. The violations observed by the PAM monitor include:

- Poor aseptic technique.
- Administration of two drugs not listed on the protocol.
- Failure to follow the protocol with respect to administration of postoperative analgesia.

The IACUC investigative team met with the investigator, the researcher who had conducted the surgery, the lab manager and mentor of the individual responsible for the noncompliance. A meeting was also held with the PAM monitor separately. A report from the investigative team was provided to the IACUC at the convened meeting held on October 10, 2019. The committee voted to impose the following corrective actions:

- Termination of the experiment observed by the post-approval monitor.
- Extensive online and hands-on veterinary retraining for the individual responsible.
- In person veterinary retraining for all individuals who perform surgery under the applicable protocol.
- Combination of two surgical protocols to reduce confusion and use of surgical checklist and revising of a surgical record template to facilitate compliance.

Based on its assessment of this explanation, OLAW understands that the Columbia University has implemented appropriate measures to correct and prevent recurrences of these problems and is now compliant with provisions of the PHS Policy.

Sincerely,

(b) (6)

Jacquelyn T. Tubbs, DVM  
Veterinary Medical Officer  
Division of Compliance Oversight  
Office of Laboratory Animal Welfare

cc: IACUC Contact  
IACUC Office Director

COLUMBIA UNIVERSITY  
IN THE CITY OF NEW YORK

EXECUTIVE VICE PRESIDENT FOR RESEARCH

December 19, 2019

Brent Morse, D.V.M.  
Director Division of Compliance Oversight  
Office of Laboratory Animal Welfare  
National Institutes of Health  
6705 Rockledge Drive  
Suite 360, MSC 7982  
Bethesda, MD 20892-7982

Re: Columbia University  
Animal Welfare Assurance # D16-00003 (A3007-01)

Dear Dr. Morse,

On August 9, 2019, Columbia University (the "University") notified the Office of Laboratory Animal Welfare ("OLAW") by telephone of an incident in which an individual was conducting mouse survival surgery not in compliance with the applicable protocol. The research was supported by the Public Health Service under NIH grant # 5R01 EY011787-18 and a subaward under grant # 1R01 MH115900-01A1.

This letter reports the results of a review of the incident and the corrective actions taken by the Institutional Animal Care and Use Committee ("IACUC").

**Background and Investigation**

On July 31, 2019, an IACUC post-approval monitor notified Dr. Mary Jo Shepherd, Executive Director of the IACUC, that an individual was conducting mouse survival surgery out of compliance with the approved protocol. The violations observed included poor aseptic technique, administration of two drugs not listed in the protocol and failure to follow the protocol with respect to administration of postoperative analgesia.

Dr. Shepherd notified the IACUC Chair when she learned of the incident and an investigation was initiated. The IACUC investigative team (Dr. Shepherd and another IACUC member) met with the principal investigator, the researcher who had conducted the surgery in question, the laboratory manager and the mentor of the individual responsible for the noncompliance. They also met separately with the post-approval monitor who made the observations.

### Corrective Actions

A report from the investigative team was provided to the IACUC and a convened meeting of a quorum of the Committee was held on October 10, 2019. Following review of the facts and discussion, the Committee voted to impose the following corrective measures:

1. The investigator was required to fully implement and continue to adhere to his plan for correction, which included termination of the experiment observed by the post-approval monitor; extensive online and hands-on veterinary retraining for the individual responsible; in-person veterinary retraining for all individuals who perform surgery under the applicable protocol; combination of two surgical protocols to reduce confusion; and use of a surgical checklist and revision of a surgical record template to facilitate compliance.

Columbia University remains committed to achievement and maintenance of the highest standards of laboratory animal care and use. If you have any further questions concerning this report, please contact Dr. Shepherd at (b) (6)

Sincerely,

(b) (6)

G. Michael Purdy, Ph.D.  
Executive Vice President for Research

cc: (b) (6)  
Brian Karolewski, D.V.M.  
MJ Shepherd, D.V.M.

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

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Thursday, December 19, 2019 1:51 PM  
**To:** Shepherd, Mary J.; OLAW Division of Compliance Oversight (NIH/OD)  
**Cc:** MJ Shepherd  
**Subject:** RE: Compliance Letter from Columbia University

Thank you for providing this final report Dr. Shepherd. 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:** Shepherd, Mary J. [mailto:ms4387@cumc.columbia.edu]  
**Sent:** Thursday, December 19, 2019 1:27 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Cc:** MJ Shepherd <ms4387@columbia.edu>  
**Subject:** Compliance Letter from Columbia University

Please see attached. Let me know if you have any questions or concerns. Thank you. MJ

Mary Jo (MJ) Shepherd, DVM, CPIA  
Executive Director IACUC  
Columbia University



## Initial Report of Noncompliance

By: *[Signature]*

Date: 8/9/19

Time: 1:45

Name of Person reporting: M.J. Shepherd, DVM

Telephone #: [Redacted]

(b) (6)

Fax #: [Redacted]

Email: [Redacted]

Name of Institution: Columbia U.

Assurance number: A3007

Did incident involve PHS funded activity? Yes

Funding component: \_\_\_\_\_

Was funding component contacted (if necessary): \_\_\_\_\_

What happened? Investigator not performing aseptic stereotactic surgery properly

Species involved: Mice

Personnel involved: Researcher

Dates and times: \_\_\_\_\_

Animal deaths: No

Projected plan and schedule for correction/prevention (if known): \_\_\_\_\_

Projected submission to OLAW of final report from Institutional Official: \_\_\_\_\_

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Case # \_\_\_\_\_