



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

October 1, 2019

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

G. Michael Purdy, Ph.D.  
Executive Vice President for Research  
Columbia University Medical Center  
535 West 116<sup>th</sup> St. – 313 Low Library MC 4310  
New York, NY 10027

Dear Dr. Purdy,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your September 19, 2019 letter regarding noncompliance with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals at Columbia University, which had been preceded by a preliminary report to OLAW on April 16, 2019. According to the information provided, our office understands that on April 9, 2019, a veterinarian notified the Institutional Animal Care and Use Committee (IACUC) that a fecal transplantation study had been performed without IACUC approval. Thirty mice were affected and seven died as a result of the procedure. The mice were on a PHS funded activity.

Immediate corrective actions consisted of euthanizing the remaining mice and initiation of an IACUC investigation. On June 13, 2019, the IACUC discussed the results of the investigation, and required the Principle Investigator to adhere to a corrective action plan that he had submitted after the incident. The plan included veterinary and regulatory training for all laboratory personnel, as well as a protocol modification and consolidation of protocols to enhance compliance. The IACUC voted to impose these measures, and the University has ensured that the grant will not be charged for the expenses relating to the unapproved activities.

Based on its assessment of this explanation, OLAW understands that measures have been taken to prevent recurrence of this problem. Your institution may additionally wish to consider enhanced post-approval monitoring to ensure that the corrective measures are effective. Please also note that results from activities that were not IACUC-approved may encounter difficulties with publication. OLAW concurs with the actions taken by your institution to comply with the PHS Policy on Humane Care and Use of Laboratory Animals. We appreciate having been informed of this matter and find no cause for further action by this office at this time.

Sincerely,

(b) (6)

Nicolette Petervary, VMD, DACAW  
Veterinary Medical Officer  
Office of Laboratory Animal Welfare

cc: IACUC Contact  
IACUC Office Director

COLUMBIA UNIVERSITY

IN THE CITY OF NEW YORK

EXECUTIVE VICE PRESIDENT FOR RESEARCH

3007-2E  
final

September 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. Wolff,

On April 19, 2019, Columbia University (the "University") notified the Office of Laboratory Animal Welfare ("OLAW") by telephone of an incident concerning the conduct of a procedure in mice without approval by the Institutional Animal Care and Use Committee ("IACUC" or the "Committee"). The research under the associated protocol was supported by the Public Health Service under NIH grant # 3U54CA163004-07.

This letter reports the results of a review of the incident and the corrective actions taken by the IACUC.

**Background and Investigation**

On April 9, 2019, a veterinarian from the Institute of Comparative Medicine ("ICM") notified Dr. Mary Jo Shepherd, Executive Director of the IACUC, that a fecal transplantation study had been conducted without IACUC approval.

Dr. Shepherd notified the IACUC Chair when she learned of the incident and an investigation was initiated. The IACUC investigative team met with the principal investigator, his laboratory manager and the researcher responsible for the conduct of the unapproved procedure to review the incident, and determined that 30 mice were used in the study. Seven animals died as a result of the procedure, and the remaining animals were euthanized after the IACUC learned of the incident. The principal investigator submitted a proposed plan of correction for the noncompliance that had occurred.

### 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 June 13, 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 regulatory and veterinary online retraining for all laboratory personnel, a protocol modification and consolidation of protocols to enhance compliance.

As required by OLAW Notice OT-OD-10-081, 'Guidance on Confirming Appropriate Charges to NIH Awards during Periods of Noncompliance for Activities Involving Animals,' the University hereby confirms that appropriate adjustments will be made to the grant supporting the research to remove charges for the unauthorized animal activities. We expect these adjustments to be completed within the next 30 days.

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)

MJ Shepherd, D.V.M.

**Na, Jane (NIH/OD) [E]**

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Friday, September 20, 2019 7:42 AM  
**To:** Shepherd, Mary J.  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: Columbia University Compliance Report

Thank you for this final report. We will send an official response soon.

Jane

Jane Na, DVM, CPIA  
Veterinary Medical Officer  
Office of Laboratory Animal Welfare  
National Institutes of Health  
Phone (301) 402-1922  
E-fax (301) 451-5609

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**From:** Shepherd, Mary J. <ms4387@cumc.columbia.edu>  
**Sent:** Friday, September 20, 2019 6:47 AM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Subject:** Columbia University Compliance Report

Attached. Please let me know if you have any questions or concerns. Thank you. MJ

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

(b) (6)



## Initial Report of Noncompliance

By: SGM

Date: 4/16/19

Time: 3:05

Name of Person reporting: M.J. Shepherd, DVM  
Telephone #: (b) (6)  
Fax #: [REDACTED]  
Email: [REDACTED]

Name of Institution: Columbia Univ.  
Assurance number: A3007

Did incident involve PHS funded activity? Yes  
Funding component: [REDACTED]  
Was funding component contacted (if necessary): [REDACTED]

What happened? Unapproved fecal transplant. 20% died.

Species involved: Mice  
Personnel involved: Researcher  
Dates and times: [REDACTED]  
Animal deaths: Yes

Projected plan and schedule for correction/prevention (if known): Veterinarian stopped procedure.

Projected submission to OLAW of final report from Institutional Official: [REDACTED]

OFFICE USE ONLY  
Case # [REDACTED]