



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 10, 2019

Re: Animal Welfare Assurance
A3523-01 [OLAW Case 2J]

Kenneth S. Polonsky, M.D.
Dean Division of Biological Sciences
and the Pritzker School of Medicine
Executive Vice President for Medical Affairs
University of Chicago
5841 S. Maryland Ave., MC 1000
Chicago, IL 60637

Dear Dr. Polonsky

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your November 22, 2019 letter reporting a serious deviation from the provisions of the *Guide for the Care and Use of Laboratory Animals* at the University of Chicago, following up on an initial report on October 15, 2019. According to the information provided, OLAW understands that a mouse had been subjected to a survival surgery not described in the approved protocol and was housed in a laboratory not approved as a satellite facility.

The immediate action taken upon discovery consisted of euthanizing the mouse. Because the incident constituted a repeat finding of noncompliance, the Institutional Animal Care and Use Committee (IACUC) requested a corrective action plan from the investigator addressing laboratory oversight and compliance. In response the investigator euthanized all animals, terminated all protocols, and stopped doing animal research.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to correct and prevent recurrence of this problem. OLAW concurs with the actions taken by the IACUC to comply with the PHS Policy on Humane Care and Use of Laboratory Animals. Please ensure that the NIH grant was not charged for any unauthorized animal activities. Thank you for keeping OLAW apprised on this matter.

Sincerely,

(b) (6)

Axel Wolff, M.S., D.V.M.
Deputy Director
Office of Laboratory Animal Welfare

cc: IACUC Chair



AT THE FOREFRONT

**UChicago
Medicine &
Biological
Sciences**

Kenneth S. Polonsky, MD
*Richard T. Crane Distinguished Service Professor
Dean of the Division of the Biological Sciences
and the Pritzker School of Medicine
Executive Vice President for Medical Affairs*

November 22, 2019

Brent Morse, D.V.M.
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
6700B Rockledge Drive, Suite 2500, MSC 6910
Bethesda, MD 20892

Re: Report of Serious Non-Compliance; Assurance Number D16-00322 (A-3523-01)

Dear Dr. Morse:

I write to provide the final report of an incident the University of Chicago IACUC determined represented a serious deviation from the provisions of the *Guide for the Care and Use of Laboratory Animals*. A preliminary report was provided by email on October 14th by (b) (6)

During the September semi-annual facility inspection, the inspection team discovered a mouse being housed in an investigator laboratory that had undergone survival surgery to mark the lymphatic system. Neither the survival surgery nor the housing within the laboratory was described in the approved animal care and use protocol. The animal was euthanized at the time of the inspection.

This was the second time the laboratory was discovered to be performing procedures not approved by the IACUC and the Committee was greatly concerned that appropriate laboratory oversight was not being provided. Therefore, the Committee requested the investigator submit a comprehensive plan for laboratory oversight that demonstrated a concern for animal welfare and would ensure compliance with approved protocols, policies and guidelines. Until an acceptable plan could be devised, the investigative group would be subjected to random laboratory inspections, restricted from removing animals from the central facilities and restricted from purchasing additional animals. The Animal Resources Center would also provide additional oversight of the animals on census and housed in the central facility to monitor their welfare. The protocol under which the animal was assigned was supported by NIH Grant R01HL128228-01A1.

In response to the concerns presented by the Committee and due to other factors, the investigator decided to terminate all animal research in the laboratory and requested expiration of all their approved animal care and use protocols. All animals associated with the protocols have been euthanized and the protocols expired. We trust that the measures taken by the Committee and the investigator to resolve this non-compliance incident are appropriate. If you require further information, please feel free to Dr. Catherine Reardon-Alulis, IACUC Chair, at (b) (6) or Dr. George Langan, Attending Veterinarian, at (b) (6)

Sincerely, (b) (6)

Kenneth S. Polonsky, MD

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Tuesday, December 10, 2019 8:50 AM
To: (b) (6) OLAW Division of Compliance Oversight (NIH/OD)
Cc: Langan, George [BSD] - ARC (glangan@bsd.uchicago.edu); Catherine Reardon Reardon-Alulis Ph.D.
Subject: RE: Final Report of Serious Deviation: University of Chicago Assurance # D16-00322 (A3523-01)

Thank you for providing this final report (b) (6) 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: (b) (6)
Sent: Monday, December 09, 2019 4:54 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Langan, George [BSD] - ARC (glangan@bsd.uchicago.edu) <glangan@bsd.uchicago.edu>; Catherine Reardon Reardon-Alulis Ph.D. <reardon@uchicago.edu>
Subject: Final Report of Serious Deviation: University of Chicago Assurance # D16-00322 (A3523-01)

Dear Dr. Wolff and Dr. Morse,

Attached please find the final report from our Institutional Official of an incident that the University of Chicago IACUC had determined to represent a serious deviation from the provisions of the *Guide for the Care and Use of Laboratory Animals*. A preliminary report had previously been provided by email (below). Thank you.

Best regards,

(b) (6)

(b) (6)

From: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>

Sent: Tuesday, October 15, 2019 12:19 PM

To: (b) (6)

Cc: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>

Subject: RE: Preliminary Report of Serious Deviation: University of Chicago Assurance # D16-00322 (A3523-01)

Thank you for this preliminary report, (b) (6) We will start a new case file and look forward to receiving the final report from the IO after the IACUC has completed its investigation.

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

From: (b) (6)

Sent: Tuesday, October 15, 2019 11:32 AM

To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>

Cc: Langan, George [BSD] - ARC (glangan@bsd.uchicago.edu) <glangan@bsd.uchicago.edu>; Catherine Reardon Reardon-Alulis Ph.D. <reardon@uchicago.edu>

Subject: Preliminary Report of Serious Deviation: University of Chicago Assurance # D16-00322 (A3523-01)

Dear Dr. Wolff,

This email is to provide a preliminary report of a recent incident involving a staff member not following the approved mouse protocol discovered on 09/04/2019 during the semi-annual facility inspections. The IACUC has determined this to represent a deviation from the provisions of the *Guide for the Care and Use of Laboratory Animals*. The IACUC has requested further information regarding the incident and this information will be reviewed by the IACUC to determine the final resolution prior to the final written report being submitted.

Thank you.
Best regards,
(b) (6)

(b) (6)