



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

June 27, 2022

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

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 May 23, 2022 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals within the animal care and use program at the University of Chicago. Your letter supplemented the information contained in an initial email report to this office on April 19, 2022. According to the information provided, OLAW understands that a cecal ligation and puncture surgery not approved by the IACUC was performed on mice. Upon notification, the responsible individual euthanized the animals and halted further experiments. An amendment to include the procedure was under review by the IACUC and the responsible laboratory member mistakenly believed that the procedure had been approved. The mice involved in this incident were supported by PHS funds.

The IACUC approved several corrective and preventive measures in response to this incident. The Principal Investigator (PI) and laboratory staff will undergo retraining regarding the importance of compliance and the consequences of noncompliance. The PI will develop a comprehensive plan to ensure that staff are aware of and compliant with approved protocol(s) and IACUC policies and guidelines. The laboratory manager will review cage cards weekly to verify that the correct protocol is assigned. Further, amendments will be reviewed at laboratory meetings to confirm approved procedures. When approved, a veterinarian will observe the cecal ligation and puncture procedure and the PI will submit a report to the IACUC on a pilot study to refine the procedure and develop appropriate endpoints to mitigate morbidity and mortality.

OLAW appreciates the consideration of this matter by the University of Chicago, which was consistent with the philosophy of institutional self-regulation. Based on the information provided, OLAW is satisfied that appropriate actions have been taken to investigate this incident and prevent recurrence. However, in future reports, please include the approximate number of animals affected.

We appreciate being informed of this matter and find no cause for further action by this office.

Sincerely,

Robyn M. Engel -S

Digitally signed by Robyn M.
Engel -S
Date: 2022.06.27 10:58:36 -04'00'

Robyn M. Engel, DVM
Animal Welfare Program Specialist
Office of Laboratory Animal Welfare

cc: IACUC contact

A3523-2R



May 23, 2022

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*. (b) (6)
(b) (6) provided a preliminary report by email on April 19, 2022.

The incident involved performing a surgical procedure (cecal ligation puncture) not approved by the Committee that resulted in morbidity and mortality. Upon being notified, the individual conducting the experiment promptly euthanized the animals and halted further experiments. An account of the events that occurred was provided by the Principal Investigator.

The amendment to include the cecal ligation puncture surgery was currently under review by Committee and the individual responsible mistakenly believe the procedure to have been approved. After discussing, the IACUC was concerned laboratory staff were not aware of procedures approved in laboratory protocols. To ensure the laboratory had an appreciation for the importance of compliance and the consequences of non-compliance, the IACUC requested the principal investigator and staff successfully complete the "Working with the IACUC" and the "Common Compliance Issues" training courses available at the AALAS Learning Library. The Committee also requested the investigator develop a comprehensive plan to ensure staff were aware of and document compliance with approved protocol(s) and IACUC policies and guidelines.

To ensure continued training and compliance with approved protocols, laboratory staff have been provided all approved protocols to review and are to ensure animals are assigned to the appropriate protocol for experimental procedures. The laboratory manager will review cage cards weekly to verify the correct protocol is assigned. As amendments are approved, they will be reviewed at laboratory meetings to confirm approved procedures.

In addition, the IACUC has requested a veterinarian observe the surgical procedure and the Principal Investigator to report on a pilot study to refine the procedure and develop appropriate endpoints to mitigate morbidity and mortality. With this framework in place, the IACUC was satisfied with the response and considers this matter resolved. NIH Grant 2P01AI097113 and internal funding supported the protocol under which the animals were assigned.

We trust that the corrective measures taken for this non-compliance incident by the IACUC are appropriate. If you require further information, please feel free to contact 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
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
The University of Chicago

Cc: Catherine Reardon-Alulis
George Langan
IACUC Office

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, June 6, 2022 6:57 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Final Report of Serious Deviation: University of Chicago Assurance # D16-00322 (A3523-01)

Thank you. We will send a response soon.
Axel Wolff

From: (b) (6)
Sent: Friday, June 3, 2022 10:28 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Catherine Reardon Reardon-Alulis Ph.D. <reardon@uchicago.edu>; glangan@bsd.uchicago.edu
Subject: [EXTERNAL] Final Report of Serious Deviation: University of Chicago Assurance # D16-00322 (A3523-01)

Dear OLAW,

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)

From: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Sent: Wednesday, April 20, 2022 6:18 AM
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 open 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: [REDACTED] (b) (6)

Sent: Tuesday, April 19, 2022 4:45 PM

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

Cc: Catherine Reardon Reardon-Alulis Ph.D. <reardon@uchicago.edu>; glangan@bsd.uchicago.edu

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

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.

Dear OLAW,

This email is to provide a preliminary report of an incident that the University of Chicago IACUC has determined to represent a serious deviation from the provisions of the *Guide for the Care and Use of Laboratory Animals*. The incident involved mice undergoing a procedure not described in the approved protocol. The IACUC has requested further information regarding the incident and will review to determine the resolution prior to the final report being submitted. Please feel free to call me at [REDACTED] (b) (6) or email me at [REDACTED] (b) (6) with questions. Thank you.

Best regards,

[REDACTED] (b) (6)

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.

Wolff, Axel (NIH/OD) [E]

A3523-2R

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, April 20, 2022 7:18 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
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 open 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, April 19, 2022 4:45 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Catherine Reardon Reardon-Alulis Ph.D. <reardon@uchicago.edu>; glangan@bsd.uchicago.edu
Subject: [EXTERNAL] Preliminary Report of Serious Deviation: University of Chicago Assurance # D16-00322 (A3523-01)

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Best regards,

(b) (6)