



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

November 5, 2021

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

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 September 30, 2021 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of Chicago following up on an initial June 14, 2021 notification by email.

According to the information provided, this Office understands that the University of Chicago Animal Care and Use Committee (ACUC) determined that instances of noncompliance occurred with respect to: failure to adhere to institutional policies/procedures and unqualified personnel conducting animal-related procedures. The final report states euthanasia was performed on adult animals by a physical method not approved by the IACUC and by an individual not appropriately trained in the procedure. In response, the Principal Investigator (PI) and staff member provided a detailed account of the event along with a corrective action plan.

Following discussion of the matter by the IACUC, the committee requested the PI and staff member successfully complete the "Working with the IACUC" and the "Common Compliance Issues" training courses available at the AALAS Learning Library. It is understood that the laboratory staff was required to attend a meeting with representatives from the IACUC to discuss the importance of compliance, common noncompliance issues, consequences of noncompliance and applying that knowledge in laboratory operations to prevent noncompliance. To ensure continued training and compliance, the laboratory staff were required to complete the following action items:

- Read the protocol on a regular basis and ask questions for clarification.
- Ensure their proposed experiment and experimental agents are approved in the protocol prior to initiation.
- Discuss recently approved amendments to the protocol at laboratory meetings.
- Document observations required by the protocol in the experimental records.
- Review record templates to ensure that they are in alignment with the approved protocol.
- Be reminded of the consequences of noncompliance.

- Be properly trained in handling the animals and the techniques described in the protocol with hands on rodent training obtained through the Animal Resources Center.

Per the report, the IACUC will periodically perform record reviews to confirm continued adherence to the approved protocol. It is noted that this research project is supported by PHS funding.

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

We appreciate being informed of these matters and find no cause for further action by this Office.

Sincerely,

Jacquelyn T.

Tubbs -S

Digitally signed by Jacquelyn T.  
Tubbs -S  
Date: 2021.11.05 12:04:54 -04'00'

Jacquelyn Tubbs, DVM, DACLAM  
Animal Welfare Program Specialist  
Division of Compliance Oversight  
Office of Laboratory Animal Welfare

cc: IACUC Contact



September 30, 2021

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 June 14, 2021.

The incident entailed the euthanasia of adult animals by a physical method not approved by the IACUC and by an individual not appropriately trained in the procedure. Upon being notified, the principal investigator and staff member promptly took responsibility, provided a detailed account of the incident and provided a corrective plan of action.

After discussing, the IACUC was concerned about whether the laboratory fully understood the seriousness of the incident and questioned the effectiveness of the corrective action plan. 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. Following completion of the training, laboratory staff was required to attend a meeting with representatives from the IACUC to discuss the importance of compliance, common non-compliance issues, consequences of non-compliance and applying that knowledge in laboratory operations to prevent non-compliance.

To ensure continued training and compliance with approved protocols, laboratory staff will:

- Read the protocol on a regular basis and ask questions for clarification.
- Ensure their proposed experiment and experimental agents are approved in the protocol prior to initiation.
- Discuss recently approved amendments to the protocol at laboratory meetings.
- Document observations required by the protocol in the experimental records.
- Review record templates to ensure that they are in alignment with the approved protocol.
- Be reminded of the consequences of non-compliance.
- Be properly trained in handling the animals and the techniques described in the protocol with hands on rodent training obtained through the Animal Resources Center.

In addition, the IACUC will periodically perform record reviews to confirm continued adherence to the approved protocols. With this framework in place, the IACUC was satisfied with the response and considers this matter resolved. NIH Grant 1U01CA198989-01 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, M.D.  
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

Cc: Catherine Reardon-Alulis  
George Langan  
IACUC Office

**Wolff, Axel (NIH/OD) [E]**

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Monday, November 1, 2021 7:39 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 for this report. We will send a response soon.

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

**From:** (b) (6)  
**Sent:** Friday, October 29, 2021 4:14 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:** 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)

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(b) (6)

**From:** OLAW Division of Compliance Oversight (NIH/OD) <[olawdco@od.nih.gov](mailto:olawdco@od.nih.gov)>  
**Sent:** Wednesday, June 16, 2021 6:30 AM  
**To:** (b) (6)  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD) <[olawdco@od.nih.gov](mailto: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:** (b) (6)  
**Sent:** Monday, June 14, 2021 8:16 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <[olawdco@od.nih.gov](mailto:olawdco@od.nih.gov)>  
**Cc:** Catherine Reardon Reardon-Alulis Ph.D. <[reardon@uchicago.edu](mailto:reardon@uchicago.edu)>; [glangan@bsd.uchicago.edu](mailto:glangan@bsd.uchicago.edu); 'iacuc@uchicago.edu' <[iacuc@uchicago.edu](mailto:iacuc@uchicago.edu)>  
**Subject:** Preliminary Report of Serious Deviation: University of Chicago Assurance #D16-00322 (A3523-01)

Dear OLAW,

This email is to provide a preliminary report on a recent 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 the euthanasia of adult mice by a method not described in the IACUC approved protocol. The IACUC is reviewing information regarding the incident and will submit a final report upon resolution. Please feel free to call me at (b) (6) or email me at (b) (6) with questions. Thank you.

Best regards,  
(b) (6)

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(b) (6)

**Wolff, Axel (NIH/OD) [E]**

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**Cc:** Catherine Reardon Reardon-Alulis Ph.D. <reardon@uchicago.edu>; glangan@bsd.uchicago.edu; 'iacuc@uchicago.edu' <iacuc@uchicago.edu>  
**Subject:** Preliminary Report of Serious Deviation: University of Chicago Assurance #D16-00322 (A3523-01)

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(b) (6)

