



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 19, 2020

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

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 your May 18, 2020 letter, received in our office on June 10th, reporting a noncompliance with the PHS Policy on the Humane Care and Use of Laboratory Animals at the University of Chicago. Your letter supplements the information provided in the initial email report on March 25, 2020. According to the information provided it is understood that a drug was administered to animals (mice) not assigned to the protocol and by a route (intravenous) that was not described in the protocol. This resulted in morbidity and mortality. The unapproved procedures performed were not supported by any federal funds.

Corrective and preventive actions included the submission of an amendment addressing the unapproved activities. It has been approved by the Committee. The investigator has implemented the following standards to ensure training and compliance with approved protocols:

- Staff must review and understand the approved protocols for the laboratory.
- Staff will review animal use as well as new amendments at weekly laboratory meetings to ensure adherence to the approved protocols. They will be reminded that performing unapproved procedures on animals is not acceptable and data obtained from unapproved animal research cannot be utilized for grants or publications.
- Staff must request in writing for investigator approval, the *in vivo* use of a new compound or procedure, justification for the use or procedure and document the section of the protocol that outlines this use. If no section of the protocol covers the use, an amendment must be submitted and approval by the IACUC confirmed before initiation of experiments.
- Staff must provide in writing the section of approved protocol(s) that covers the use of animals described in grants and/or manuscript.

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 the incident, correct the non-compliance, and prevent recurrence. OLAW concurs that the incident warranted reporting. Although this activity was not PHS funded, the application of the expectations of the PHS Policy across the animal care and use program reduces any potential appearance of a double standard.

Page 2 – Dr. Polonsky
June 19, 2020
OLAW Case A3523-2M

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

Sincerely,

Brent C. Morse -S

Digitally signed by Brent C.

Morse -S

Date: 2020.06.19 08:26:49 -04'00'

Brent C. Morse, DVM
Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC Contact



May 18, 2020

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 March 25th from [REDACTED] (b) (6)

The incident entailed the administration of a drug to animals not assigned to the protocol describing the drug use and by a route (intravenous) not approved by the Committee that resulted in morbidity and mortality. Upon being notified, the individual conducting the experiment promptly took responsibility for their actions, halted all further experiments and provided a detailed account of the events that occurred.

After discussing the incident, the Committee required confirmation in writing from the investigator additional studies would not be conducted until an amendment could be reviewed and approved. The required amendment needed to outline the experimental procedure, provide justification for performing the study, and include appropriate early removal criteria and monitoring frequencies to ensure the adverse consequences would not be repeated. The Committee also requested the investigator develop a comprehensive plan to ensure appropriate training and supervision of staff as well as document compliance with approved protocol(s) and IACUC policies and guidelines.

The requested amendment has been submitted and approved by the Committee. The investigator has implemented the following standards to ensure training and compliance with approved protocols:

- Staff must review and understand the approved protocols for the laboratory.
- Staff will review animal use as well as new amendments at weekly laboratory meetings to ensure adherence to the approved protocols. They will be reminded that performing unapproved procedures on animals is not acceptable and data obtained from unapproved animal research cannot be utilized for grants or publications.
- Staff must request in writing for investigator approval, the *in vivo* use of a new compound or procedure, justification for the use or procedure and document the section of the protocol that outlines this use. If no section of the protocol covers the use, an amendment must be submitted and approval by the IACUC confirmed before initiation of experiments.
- Staff must provide in writing the section of approved protocol(s) that covers the use of animals described in grants and/or manuscript.

With this framework in place, the IACUC was satisfied with the response and considers this matter resolved. The unapproved procedures performed were not supported by any federal funds.

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]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, June 12, 2020 7:17 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, (b) (6) We will respond soon.
Axel Wolff

From: (b) (6)
Sent: Wednesday, June 10, 2020 5:35 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)

(b) (6)

From: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Sent: Thursday, March 26, 2020 6:07 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 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: Wednesday, March 25, 2020 4:21 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: 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 administration of an agent to mice by a method not approved by the IACUC. A final written report will be submitted upon resolution of the incident. If you need further information please feel free to call me at (b) (6) or email at (b) (6). Thank you.

Best regards,
(b) (6)

(b) (6)

Wolff, Axel (NIH/OD) [E]

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Thank you for this preliminary report, (b) (6). We will open a new case 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

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Best regards,
(b) (6)

(b) (6)