



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

March 16, 2020

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

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 March 9, 2020 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 report on November 21, 2020. According to the information provided, OLAW understands that a nonhuman primate on approved fluid restriction failed to receive the daily allotment of fluid for one day. Miscommunication between laboratory staff members was responsible for the incident.

The corrective actions consisted of having the veterinarian examine the monkey, analyzing a blood sample, and finding the animal to be in good health. The veterinary staff counseled the Principal Investigator and staff and a new standard operating procedure (SOP) was developed addressing fluid restriction. Veterinary technicians will now observe all fluid restricted animals to ensure that sufficient fluid was provided. Research, veterinary, and animal care staff have all been trained on the SOP.

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 institution to comply with the PHS Policy.

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*

March 9, 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 November 21st from (b) (6)

An investigator self-reported that a nonhuman primate had not received the protocol approved amount of fluid in a 24 hour period due to a miscommunication between lab members. The protocol is approved for fluid regulation and laboratory staff are responsible for providing the proper amount of fluids to the animal. A clinical evaluation by the veterinarian found the animal to be bright, alert, responsive, moving around without difficulty and no motor or proprioceptive deficits. Analysis of blood samples indicated no adverse effects.

Veterinary staff met with the principal investigator and staff responsible to discuss the seriousness of the issue and determine how the incident occurred. In addition, the Animal Resources Center has developed a standard operating procedure for nonhuman primates that are water restricted in which veterinary technicians will observe the animals in the afternoon and ensure sufficient fluid has been provided. Principal investigators, laboratory staff, veterinary technicians and animal care technicians have been trained on the SOP. The protocol under which this animal was assigned is supported by internal funding and NIH Grant #R01 EY019041.

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

cc: Catherine Reardon-Alulis
George Langan
IACUC Office

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, March 16, 2020 7:24 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 send a reply soon.

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

From: (b) (6)
Sent: Friday, March 13, 2020 1:09 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: Thursday, November 21, 2019 8:11 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: (b) (6)
Sent: Thursday, November 21, 2019 8:34 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Catherine Reardon Reardon-Alulis Ph.D. <reardon@uchicago.edu>; Langan, George [BSD] - ARC
<glangan@bsd.uchicago.edu> <glangan@bsd.uchicago.edu>
Subject: Preliminary Report of Serious Deviation: University of Chicago Assurance # D16-00322 (A3523-01)

Dear Dr. Morse,

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 a nonhuman primate that had a deviation in the approved protocol. We are investigating and developing a solution to prevent a reoccurrence. A final written report will be submitted upon resolution of the incident. Thank you.

Best regards,

(b) (6)

(b) (6)

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Thursday, November 21, 2019 9:11 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)

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

From: (b) (6)
Sent: Thursday, November 21, 2019 8:34 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Catherine Reardon Reardon-Alulis Ph.D. <reardon@uchicago.edu>; Langan, George [BSD] - ARC (glangan@bsd.uchicago.edu) <glangan@bsd.uchicago.edu>
Subject: Preliminary Report of Serious Deviation: University of Chicago Assurance # D16-00322 (A3523-01)

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Best regards,
(b) (6)

(b) (6)