



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

March 21, 2019

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

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 12, 2019 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of Chicago. According to the information provided, OLAW understands that a nonhuman primate on an approved fluid restriction study failed to receive the approved amount of fluid over a weekend, following up on an initial telephone report on March 19, 2019. Miscommunication between laboratory staff led to no additional water being given for two days, although a full water bottle had been provided on Friday.

The immediate action taken upon discovery consisted of providing water and having the veterinarian examine the monkey. The animal was found to be doing well and was given unlimited water for two weeks and continued to be healthy. The Principal Investigator and staff were counseled and a plan was put in place to ensure that the animals receive the approved fluid amount daily.

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**

A3523-2H
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 12, 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 phone on February 27th from (b) (6)

On January 14th an investigator self-reported that a nonhuman primate had not received the protocol approved amount of fluid over a weekend. The protocol is approved for fluid regulation and laboratory staff are responsible for providing the proper amount of fluids to the animal. The animal underwent training each day of the prior week (Mon-Fri) after which treats and fluid were provided. The animal was provided a full water bottle on Friday afternoon but due to a miscommunication between laboratory staff, the water bottle was not replenished on Saturday or Sunday. On Monday afternoon, upon realizing the animal had not received replenishment of the water bottle, a staff member initially provided a small amount of water before placing a full bottle of water on the cage and paging the on-call veterinarian. A clinical evaluation by the veterinarian found the animal to be bright, alert, responsive and eating. The animal remained on ad libitum fluid for the following two weeks and did not present with any clinical symptoms of poor physical or psychological health.

ARC health checks on Saturday and Sunday found the animal to be bright, alert, responsive, eating the daily ration of biscuits and consuming all treats offered. Urine and fecal material was present in the waste pan. Interviews with veterinary technicians and laboratory staff revealed the animal typically consumes approximately half a water bottle each day. Based upon this observation, the IACUC surmised the full bottle provided on Friday may have lasted for the two day period.

Veterinary staff met with the principal investigator and staff responsible to discuss the seriousness of the issue, determine how the incident occurred and evaluate methods together to prevent this from reoccurring. The principal investigator discussed the incident with all staff at a lab meeting and developed a plan to ensure animals receive the protocol approved amount or ad libitum fluid daily. The IACUC reviewed this plan and was satisfied with the response and considers this matter resolved. The

protocol under which this animal was assigned is supported by internal funding and NIH Grant #R01EY019041.

The incident was self reported as a critical noncompliance to the USDA Veterinary Medical Officer (VMO) for the University of Chicago by the Attending Veterinarian.

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 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: Wednesday, March 20, 2019 6:54 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Final Report of Serious Deviation: Assurance #D16-00322 (A3523-01)

Thank you for this report, (b) (6) We will send a response soon.

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

(b) (6)

Sent: Tuesday, March 19, 2019 11:36 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: Final Report of Serious Deviation: Assurance #D16-00322 (A3523-01)

Dear 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 been provided by phone on February 27th. Thank you.

Best regards,

(b) (6)

(b) (6)



Initial Report of Noncompliance

By: 

Date: 3/19/19

Time: 3:40

Name of Person reporting (b) (6)

Telephone #: (b) (6)

Fax #:

Email:

Name of Institution: U. Chicago

Assurance number: A3523

Did incident involve PHS funded activity? Yes

Funding component: _____

Was funding component contacted (if necessary): _____

What happened? One NHP's water bottle not refilled over weekend

Species involved: NHP

Personnel involved: _____

Dates and times: _____

Animal deaths: No

Projected plan and schedule for correction/prevention (if known): _____

Projected submission to OLAW of final report from Institutional Official:

430d.

OFFICE USE ONLY

Case # _____