

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 <u>Telephone</u>: (301) 496-7163 <u>Facsimile</u>: (301) 480-3387

August 23, 2021

Re: Animal Welfare Assurance A3646-01 [OLAW Case 1S]

Dr. Jon Reuter Assistant Vice Chancellor for Research Integrity and Compliance University of Colorado – Boulder 3100 Marine Street, UCB 563 (b) (4) Boulder, CO 80309

Dear Dr. Reuter,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your August 10, 2021 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of Colorado - Boulder. This letter had not been preceded by a preliminary report to OLAW.

According to the information provided, this Office understands that the CU Boulder Animal Care and Use Committee (ACUC) determined that instances of noncompliance occurred with respect to: protocol noncompliance related to human error. The final report states on July 16, 2021, a graduate student performed a protocol approved surgery on a prairie vole. The animal began losing weight following surgery, and despite administration of supportive care, the animal was found dead on July 23rd. Investigative results revealed the lab member administered the stock solution of dexamethasone, and not the diluted solution on post-operative (post-op) days 3 and 4. The report states necropsy findings were unremarkable and did not reveal the cause of death.

In response to the incident, the student may not perform the surgical procedure independently until retraining has occurred. Then, the Attending Veterinarian will observe the individual prior to approval for any independent work. The lab has confirmed the standard operating procedures (SOPs) describing post-op care stated the correct drug dosage in mg/kg. It is understood all lab members were reminded where to locate these SOPs and have been instructed to include concentration of administered medications on post-operative forms.

It is noted that this project is supported by NSF funding. Based on its assessment of this explanation, OLAW understands that the University of Colorado - Boulder 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 Jacquelyn Tubbs, Date: 2021.08.23 15:34:12 -04'00' Jacquelyn Tubbs, DVM, DACLAM Animal Welfare Program Specialist Division of Compliance Oversight Office of Laboratory Animal Welfare

cc: IACUC Contact Robert M. Gibbens, DVM, Director, Animal Welfare Operations



Jon Reuter, Assistant Vice Chancellor for Research Integrity and Compliance 4845 Pearl East Circle, Suite 200 UCB 563, Boulder, CO 80309

jon reuter@colorado.edu

3646 - 15

t 303 735-5809

August 10, 2021

The University of Colorado Boulder, Assurance No. D16-00388, provides the report listed below.

Protocol: 2435 Species: Voles Funds: NIH DP2OD026143, NIH U01 NS099577, & NSF IOS-1827790, NSF IOS-2045348

On 7/16/2021 a graduate student performed an IACUC approved surgery on a prairie vole. Following surgery, the animal gradually began losing weight, but remained active. Despite supportive care by the veterinary team, the animal was found dead on 7/23. Investigation revealed that a lab member had mistakenly administered the stock solution of dexamethasone, rather than the diluted solution, on post-operative days 3 and 4. A necropsy performed by the Attending Veterinarian did not reveal any abnormalities that definitively identified a cause of death.

This protocol noncompliance was due to human error. In order to address this issue, the responsible student has been prevented from performing surgical procedure independently until retraining has occurred. Specifically, they will work under direct supervision of senior lab members and the PI for at least 12 successful surgical procedures (including post-op). The Attending Veterinarian will then observe them prior to approval for any independent work. In addition, the lab has confirmed that the SOPs covering post-operative care explicitly state the correct drug dosage in mg/kg, and include an example calculation for administration. All lab members have been reminded where to find these SOPs in hard copy and electronically. Lab members have also been instructed to include the concentration of administered medications on post-operative forms.

CU Boulder maintains its commitment to the health and welfare of animals used in research. Should you have any questions regarding this report, please contact Christopher A. Lowry, PhD, IACUC Chair at christopher.lowry@colorado.edu or Althea R. Lantron, IACUC Director, at althea.lantron@colorado.edu.

Sincerely,

DocuSigned by (b)(6)4125465D4B0945A.

Jon Reuter, Assistant Vice Chancellor of Research Integrity and Compliance

Cc: Christopher A. Lowry, IACUC Chair Althea R. Lantron, Director, IACUC Director Sara Hashway, Director, Office of Animal Resources

Wolff, Axel (NIH/OD) [E]

From:	OLAW Division of Compliance Oversight (NIH/OD)
Sent:	Friday, August 13, 2021 7:24 AM
То:	IACUC Office
Cc:	OLAW Division of Compliance Oversight (NIH/OD)
Subject:	RE: Reportable Incident

Thank you for this report. We will send a response soon.

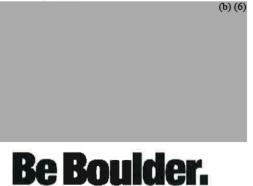
Axel Wolff, M.S., D.V.M. Deputy Director, OLAW

From: IACUC Office <iacucoffice@colorado.edu>
Sent: Thursday, August 12, 2021 1:23 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Jon D Reuter <Jon.Reuter@Colorado.EDU>; Sara Hashway <Sara.Hashway@colorado.edu>; Christopher Lowry
<christopher.lowry@colorado.edu>; Althea Lantron <Althea.Lantron@Colorado.EDU>
Subject: Reportable Incident

Dear OLAW,

Please find attached the final report for an incident that we have found reportable.

Thanky	γou,
--------	------



University of Colorado Boulder

Obtained by Rise for Animals. Uploaded to Animal Research Laboratory Overview (ARLO) on 10/07/2022