

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 MSC 6910 Bethesda, Maryland 20817 <u>Telephone</u>: (301) 496-7163 <u>Facsimile</u>: (301) 480-3387

July 23, 2021

Re: Animal Welfare Assurance A3434-01 [OLAW Case S]

Dr. Pablo Debenedetti Dean for Research Princeton University 91 Prospect Avenue Princeton, NJ 08544

Dear Dr. Debenedetti,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your July 1, 2021 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Princeton University. Your letter supplemented the information contained in an initial telephone report to this office on June 10, 2021. According to the information provided, OLAW understands that on April 5, 2021 a mouse was found dead by a Laboratory Animal Resources (LAR) veterinary technician. Upon further review of the surgical log from April 2, 2021, it was noted that the animal presented with clinical concerns the following day after surgery. The animal was given injections of Meloxicam and Saline that were not approved in the IACUC protocol. LAR veterinary services was not contacted for appropriate guidance, as described in the approved IACUC protocol for post-op monitoring. The animal activity the animal was assigned to was funded by the PHS.

Corrective actions included the PI counseling all laboratory members regarding the importance of following the IACUC approved protocol, post-operative care and monitoring, and the importance of notifying Veterinary Services with any concerns. Re-training was conducted for the entire lab, focusing on IACUC, compliance, and veterinary expectations. A post-approval monitor is also currently working with the lab to help them continue to remain in compliance, answer questions, and assist with amendment submissions as needed.

OLAW appreciates the prompt consideration of this matter by Princeton University, 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 and to prevent recurrence. 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: 2021.07.23 13:32:25 -04'00'

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

cc: IACUC Chair

PrincetonOffice of theResearchDean for Research

Pablo G. Debenedetti

Dean for Research Class of 1950 Professor in Engineering & Applied Sciences

Princeton University 91 Prospect Avenue Princeton, NJ 08540

T 609.258.5480 F 609.258.5599 E pdebene@princeton.edu

July 1, 2021

Brent Morse, DVM, DACLAM Director, Division of Compliance Oversight Office of Laboratory Animal Welfare National Institutes of Health 6700B Rockledge Drive, Suite 2500, MSC 6910 Bethesda, MD 20892 olawdco@mail.nih.gov

Re: Report of Non-Compliance Princeton University/Assurance No. A3434

Dear Dr. Morse:

Princeton University provides this report regarding a non-compliance incident presented to the IACUC at a fully convened meeting on May 20, 2021. A preliminary report was made to you by Stuart Leland, DVM, DCLAM, Director of Research Integrity and Assurance (RIA) via telephone on June 10, 2021.

On April 5, 2021 a mouse was found dead by a Laboratory Animal Resources (LAR) veterinary technician. Upon further review of the surgical log from April 2, 2021, it was noted that the animal presented with clinical concerns the following day after surgery. The animal was given injections of Meloxicam and Saline that were not approved in the IACUC protocol. LAR veterinary services was not contacted for appropriate guidance, as described in the approved IACUC protocol for post-op monitoring.

The Principal Investigator (PI) attended the IACUC meeting and has been very responsive to any questions by the IACUC. The PI has been in communication with all laboratory members regarding the importance of following the IACUC approved protocol, post-operative care and monitoring, and the importance of notifying Veterinary Services with any concerns.

RIA and LAR will be providing a re-training on July 2, 2021 for the entire lab focusing on IACUC, compliance, and veterinary expectations. RIA's post-approval monitor is also currently working with the lab to help them continue to remain in compliance, answer questions, and assist with amendment submissions as needed.



research.princeton.edu

Princeton University is committed to protecting the welfare of animals used in research and teaching. We appreciate the guidance and assistance provided by OLAW in this regard. Should you have any additional questions regarding this report, please contact Stuart Leland, Research Integrity and Assurance at ^{(b) (6)} Thank you for your time and attention to this matter.

With Best Regards,

(b) (6)

Pablo G. Debenedetti Institutional Official

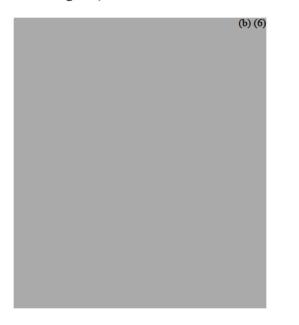


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Wolff, Axel (NIH/OD) [E]

From: Sent:	OLAW Division of Compliance Oversight (NIH/OD) Monday, July 19, 2021 7:35 AM
To:	
Cc:	OLAW Division of Compliance Oversight (NIH/OD)
Subject:	RE: Princeton University Assurance No. A3434
	(h) (f)
Thank you for this report,	(b) (6) We will send a response soon.
Axel Wolff, M.S., D.V.M. Deputy Director, OLAW	
From:	(b) (6)
Sent: Monday, July 12, 2021 10:25 AM	
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov></olawdco@od.nih.gov>	
Cc: Pablo G. Debenedetti <pdebene@princeton.edu></pdebene@princeton.edu>	
Subject: Princeton University Assurance No. A3434	
Dear Dr. Morse,	
Please accept the attached letter on behalf of Princeton University Assurance No. A3434.	

Kind Regards,



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Initial Report of Noncompliance

By: BCM

Date: 6/10/2021

Time: 1:55

Name of Person reporting: Stuart Leland, AV Telephone #: (b) (6) Fax #: Email:

 Name of Institution:
 Princeton Univ.

 Assurance number:
 A3434

Did incident involve PHS funded activity? __yes____ Funding component: __?____ Was funding component contacted (if necessary): _____

What happened: One mouse found dead after approved surgery. Lab had attempted clinical care with unapproved meds. Did not contact Vet even though protocol said they would.

Species involved: Mouse Personnel involved: Researcher Dates and times: April 5, 2021 Animal deaths: yes

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

Projected submission to OLAW of final report from Institutional Official:

< 60 days

OFFICE USE ONLY Case #