



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive – MSC 7982
Bethesda, Maryland 20892-7982
Home Page: <http://grants.nih.gov/grants/olaw/olaw.htm>

FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive
Bethesda, Maryland 20817
Telephone: (301) 496-7163
Facsimile: (301) 402-7065

March 5, 2018

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

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 February 28, 2018 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Princeton University, following up on an initial telephone report on February 23, 2018. According to the information provided, OLAW understands that twenty mice sustained hind limb paralysis after being subjected to an unapproved procedure. The sick mice were not reported to the veterinary staff in accordance with institutional procedures and fifteen mice were further subjected to an imaging procedure although the veterinarian had directed euthanasia.

The corrective actions consisted of the Institutional Animal Care and Use Committee suspending the animal use privileges for two of the investigators involved. Following the suspension the investigators will undergo counseling and retraining. The Principal Investigator was issued a letter of counsel. The PHS/NIH grant will not be charged for any unauthorized animal activities.

Based on the information provided, OLAW is satisfied that appropriate actions have been taken to investigate, correct, and prevent recurrence of the noncompliance. We appreciate having been informed about this matter and find no cause for further action by this Office.

Sincerely,

(b) (6)

Axel Wolff, M.S., D.V.M.
Deputy Director
Office of Laboratory Animal Welfare

cc: IACUC Chair

Research

Dean for Research

Pablo DeBenedetti
Dean for Research
Class of 1950 Professor
in Engineering and Applied Science

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February 28, 2018

Axel Wolff, D.V.M.
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
Rockledge 1, Suite 360, MSC 7982
6705 Rockledge Drive
Bethesda, MD 20892-7982
olawdoc@mail.nih.gov
(sent via email)

Re: Report of Non-Compliance
Princeton University/Assurance No. A3434
NIH Grant No. 5R01CA212410-02

Dear Dr. Wolff:

Princeton University provides this report regarding a non-compliance and animal welfare incident involving the above listed grant number.

On January 26, 2018, a Laboratory Animal Resources (LAR) Veterinary Technician observed twenty mice with left hind limb paralysis resulting from a procedure that was not approved on an IACUC protocol. During the identification, reporting and treatment of these mice, the researchers did not follow accepted procedures outlined in standard operating procedures (SOP) and policies. The clinical veterinarian recommended that the mice be euthanized. Five of the mice were euthanized immediately but fifteen of the mice underwent an additional imaging procedure under anesthesia before being euthanized later that day.

The Attending Veterinarian (AV) and the Director, Research Integrity and Assurance (RIA) met with the Principal Investigator on January 31, 2018 to gather additional details. The incident was presented to the IACUC at a fully convened meeting on February 8, 2018.

It was determined by the IACUC that this incident constituted a protocol non-compliance, as well as an animal welfare concern. Despite previous training on the requirements for IACUC review and approval of all procedures to be performed on animals and how to identify, report, and treat sick animals, the procedure performed on the mice had not been approved by the IACUC and the researchers failed to properly follow the SOP on reporting sick animals. The researchers also did not follow the IACUC policy that outlines the authority of the AV. The



researchers also did not follow the IACUC policy that outlines the authority of the AV. The committee unanimously voted to restrict the researcher who performed the unapproved procedure from conducting any animal work for a three month period and restrict the second researcher from conducting any animal work for a one month period. After the completion of the restriction of animal activities, a meeting with the AV and a representative from RIA will be scheduled with both researchers to discuss the recommencement of their animal-related work. Additional training will be provided as needed.

A letter was sent to the PI on behalf of the IACUC outlining the non-compliance issues, animal welfare concerns, and the risk to the animal care program at the University. The PI acknowledged the letter and takes these issues very seriously. We will continue to work with the PI to ensure the highest level of animal welfare and compliance. The PI has agreed to refund any NIH monies that were used to support this unapproved procedure using internal funds.

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 (b) (6) 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



Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, March 05, 2018 10:16 AM
To: (b) (6) OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Princeton University Assurance No. A3434

Thank you for this report. We will send an official response soon.

Regards, Brent Morse

Brent C. Morse, DVM, DACLAM
Acting Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health

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From: (b) (6)@princeton.edu]
Sent: Friday, March 02, 2018 9:00 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: Princeton University Assurance No. A3434

From: (b) (6)
Sent: Thursday, March 01, 2018 4:05 PM
To: 'olawdoc@mail.nih.gov' <olawdoc@mail.nih.gov>
Cc: (b) (6)@exchange.Princeton.EDU>; Pablo G. Debenedetti <pdebene@exchange.Princeton.EDU>
Subject: Princeton University Assurance No. A3434

Dear Dr. Wolff,

Please accept the attached letter on behalf of Princeton University Assurance No. A3434.

Kind Regards,

(b) (6)

(b) (6)



Initial Report of Noncompliance

By: andDate: 2/23/18Time: 12:00Name of Person reporting: (b) (6)Telephone #: (b) (6)

Fax #:

Email:

Name of Institution: PRINCETON UAssurance number: A3434Did incident involve PHS funded activity? Yes

Funding component: _____

Was funding component contacted (if necessary): NCI

What happened?

Procedure performed w/ out approval, mice got hind limb
paralysis from injection.

Species involved: Mice

Personnel involved:

Dates and times:

Animal deaths:

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

Euthanize 20 mice, suspend person involved
Counsel, retrain

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY

Case # _____