



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE  
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

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

FOR EXPRESS MAIL:

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

August 28, 2018

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

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 August 24, 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 July 17, 2018. According to the information provided, OLAW understands that research staff failed to follow the post-procedural care outlined in the approved protocol for a nonhuman primate study. The monitoring plan prescribed by the veterinarian was also not followed. The person responsible for animal monitoring was away from the institution and did not arrange for someone else to do it. There were no negative impacts on the monkeys.

The corrective actions consisted of counseling the Principal Investigator (PI) and co-PI, issuing a letter of counsel to the PI from the Institutional Animal Care and Use Committee (IACUC), and having the Institutional Official discuss the matter with the PI. The laboratory implemented a check list to ensure adequate animal care during the absence of staff, veterinary and Research Integrity and Assurance staff are providing additional training and assessing competency, veterinary staff will assess the primates quarterly, and the laboratory was placed on enhanced post-approval monitoring.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to correct and prevent recurrence of the problem. OLAW concurs with the actions taken by the IACUC 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  
Robert Gibbens, D.V.M., USDA-APHIS-AC

Princeton > Office of the  
Research Dean for Research

Pablo G. Debenedetti

Dean for Research  
Class of 1950 Professor  
In Engineering &  
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Princeton, NJ 08540

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pdebene@princeton.edu

August 24, 2018

Neera Gopee, DVM, PhD  
Veterinary Medical Officer  
Office of Laboratory Animal Welfare  
National Institutes of Health  
6700B Rockledge Drive, Suite 2500, MSC 6910  
Bethesda, MD 20892  
olawdco@mail.nih.gov  
(sent via email)  
Re: Report of Non-Compliance  
Princeton University/Assurance No. A3434

Dear Dr. Gopee,

Princeton University provides this report regarding a non-compliance incident involving PHS-funded research that was presented to the IACUC at a fully convened meeting on June 21, 2018.

On May 27, 2018, the Attending Veterinarian (AV) was called to assess a macaque that presented with mild facial swelling. The animal responded favorably to medical treatment and made a full recovery. Upon a review of the medical records, it was noted that the research staff failed to follow the IACUC protocol for post-procedural care and also failed to follow the veterinarian-prescribed monitoring plan to perform monthly MRIs.

It was determined by the IACUC that these incidents constituted a protocol non-compliance and a failure to follow veterinary-prescribed monitoring instructions. There were no serious animal welfare concerns or direct effects on animal welfare resulting from these incidents.

The Director and Assistant Director of Research Integrity and Assurance (RIA) met with the Principal Investigator (PI) and Co-Investigator on July 9, 2018 to gather additional details and discuss potential corrective actions. It was determined that the lab member responsible for this nonhuman primate (NHP) was off-campus during this period and therefore did not perform post-procedural care nor make arrangements for someone else to perform this care. These noncompliant issues were reported to Dr. Neera Gopee at OLAW on July 17, 2018 via a telephone call by the Director, RIA. A self-report was also made to USDA Veterinary Medical Officer, Dr. Jessica Gowins, on July 19, 2018 via a telephone call by the Director and Assistant Director, RIA as per the Tech Note dated December 2017, "Incentives for Identifying, Reporting, Correcting, and Preventing Noncompliance with the Animal Welfare Act."

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**Wolff, Axel (NIH/OD) [E]**

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Monday, August 27, 2018 7:12 AM  
**To:** Stuart E. Leland  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: Report of Noncompliance

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

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

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**From:** Stuart E. Leland [mailto:sleland@Princeton.EDU]  
**Sent:** Friday, August 24, 2018 10:25 AM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Cc:** Pablo G. Debenedetti <pdebene@Princeton.EDU>; (b) (6)  
(b) (6) Stuart E. Leland <sleland@Princeton.EDU>; (b) (6)  
(b) (6)  
**Subject:** Report of Noncompliance

To Whom It May Concern:

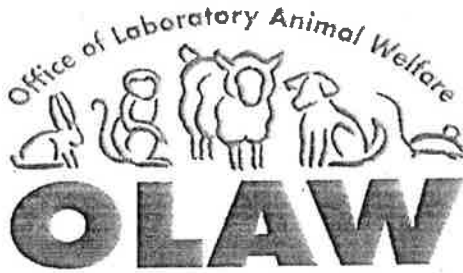
Please accept this report of noncompliance from Princeton University, assurance number A3434.

Please reach out to me if you have any further questions or require clarification.

Respectfully Submitted,

Stu

Stuart Leland, DVM, DACLAM  
Director, Research Integrity and Assurance  
Princeton University  
(b) (6)



## Initial Report of Noncompliance

By: Neena GoparDate: 07-07-18Time: 2:56 PMName of Person reporting: Servant LaladTelephone #: (b) (6)

Fax #:

Email:

Name of Institution: Purdue UniversityAssurance number: A3434-01Did incident involve PHS funded activity? Yes

Funding component: \_\_\_\_\_

Was funding component contacted (if necessary): \_\_\_\_\_

What happened?

Record review showed that ① PI failed to follow OAC this time  
 to X-ray animal on a monthly basis and ② failed to follow protocol  
 regarding post-procedure care

Species involved: non-human primatePersonnel involved: Research personnel

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:

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Case # \_\_\_\_\_