

July 2, 2024

Roxanne Mullaney, D.V.M.
Deputy Administrator
Animal and Plant Health Inspection Service
U.S. Department of Agriculture

Via e-mail: Roxanne.C.Mullaney@usda.gov

Dear Dr. Mullaney:

Thank you in advance for your time. I'm writing on behalf of People for the Ethical Treatment of Animals—PETA entities have more than 9 million members and supporters globally—to request that the U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS) launch an investigation through Investigative and Enforcement Services of the University of Washington (UW; 91-R-001) and the affiliated Washington National Primate Research Center (WaNPRC). Recently reported violations at the research facility's Institutional Animal Care and Use Committee (IACUC) meeting, along with records obtained and analyzed by PETA, reveal a troubling workplace culture in which workers are afraid to report serious animal welfare incidents. UW's recent removal of Michele Basso as director of the WaNPRC, following a string of federal Animal Welfare Act (AWA) violations, indicates an institution that's not demonstrating success at preventing critical animal welfare issues. Your former colleague Dr. Gibbens arrived at this same conclusion in mid-2021 concerning similar serious deficiencies, and—as you will see below the change in leadership in late 2021 at the WaNPRC appears to have done nothing to improve compliance at this facility.

Monkey Suffered From Seizures—Not Reported Before Amendment Approved for Second Brain Surgery

As reported at the June 2024 IACUC meeting, on August 2, 2023, laboratory staff performed a craniotomy to insert viral vectors into the brain of a 22-year-old pig-tailed macaque. The software for the robotic arm they were using malfunctioned partway through the surgery. After the surgery, the monkey had a seizure and lost control of the left side of her body. Subsequently, she experienced seizures, despite being medicated. The attending veterinarian noted in the meeting that it's very rare for monkeys to have seizures after intercranial injections. Yet these unusual and serious clinical signs weren't immediately reported by the principal investigator (PI) or WaNPRC veterinary staff to the attending veterinarian (AV), the Office of Animal Welfare, or the IACUC, as required. Through analysis of necropsy reports that PETA has obtained via public records requests, we were able to determine that Basso, then the director of the WaNPRC, was the PI associated with this monkey. (See Enclosure 1.)

According to the report given by the AV during the June 2024 IACUC meeting, on August 8, 2023, Basso and her lab filed an amendment to the experimental protocol seeking approval to do a second surgery in order to finish

PEOPLE FOR THE ETHICAL TREATMENT OF ANIMALS

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- PETA France
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- PETA Netherlands
- PETA Foundation (U.K.)

the viral vector injections, citing equipment failure during the first surgery but without mentioning in its filed amendment the seizures that the animal had endured. This amendment was approved by the IACUC on August 22, and the monkey was cleared for surgery the next day. On August 23, the second surgery took place. The monkey didn't recover and was declared braindead. The necropsy report found that the monkey had a brain clot at the brain stem that had hemorrhaged. The AV stated in the meeting that the hemorrhage was likely a result of one or both surgeries. Histology was declined by the PI, which made it impossible for the AV to determine which surgery may have caused the clot.

An anonymous whistleblower reported the seizures to the AV only recently. When asked about the incident in the IACUC meeting, the AV said that she didn't know why the seizures hadn't been reported in a timely manner, as they should have been, and that "this was reported to the AV just last month anonymously and that person was very fearful of making that report at that time [T]hat may have played a role in it not getting reported in a timely manner."

The incident also apparently violates the AWA and the associated Animal Welfare Regulations. Under the AWA, "It shall be the responsibility of the research facility to ensure that all scientists, research technicians, animal technicians, and other personnel involved in animal care, treatment, and use are qualified to perform their duties. This responsibility shall be fulfilled in part through the provision of training and instruction to those personnel." 9 CFR § 2.32(a). An environment in which an amendment is submitted without complete information, a second surgery is performed on a monkey under adverse conditions, and staff don't report animal welfare concerns indicates that UW isn't ensuring that personnel are qualified to perform their duties.

The AWA also instructs that "[e]ach research facility shall assure that the attending veterinarian has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use." 9 CFR § 2.33(a). Clearly, when according to the information presented in the June 2024 IACUC meeting, the seizures weren't reported to the AV—and when the whistleblower who did ultimately report the seizures indicated being fearful about doing so—UW's animal oversight entities, including the IACUC, OAW, and Institutional Official, had failed to ensure that the AV had appropriate authority to provide adequate veterinary care.

These failures additionally suggest that the IACUC is not fulfilling its functions under the AWA, which requires that the committee "[r]eview, and, if warranted, investigate concerns involving the care and use of animals at the research facility resulting ... from reports of noncompliance received from laboratory or research facility personnel or employees." 9 CFR § 2.31(c)(4). If people working in the laboratory are fearful about reporting animal welfare concerns, the IACUC is unable to investigate concerns. Furthermore, if concerns related to the condition of an animal aren't relayed to the IACUC, it can't properly review activities involving animals as required by 9 CFR § 2.31(d).

Geriatric Monkeys Trucked Nearly 3,000 Miles

As reported at the June IACUC meeting, on April 25, 2024, geriatric monkeys arrived at the WaNPRC. These primates had numerous age-related diseases and previously endured long-term cognitive experiments at another laboratory. At least one of them had undergone a major experimental surgery at this lab. The UW PI responsible for bringing these monkeys for continued cognitive experiments had failed to list where they came from and the prior major operative procedure on the protocol, as was required.

The AWA states the following:

No animal will be used in more than one major operative procedure from which it is allowed to recover, unless (A) Justified for scientific reasons by the principal investigator, in writing; (B) Required as routine veterinary procedure or to protect the health or well-being of the animal as determined by the attending veterinarian; or (C) In other special circumstances as determined by the [APHIS] Administrator on an individual basis. 9 CFR § 2.31(d)(1)(x).

According to the information presented during the June 2024 IACUC meeting, the PI had failed to provide scientific justification, the surgery was experimental, and a special circumstance exception had not been granted by APHIS.

The origin of the shipment wasn't disclosed during the IACUC meeting, but PETA was able to identify this shipment from records we had previously received through open records requests. (See Enclosure 2.) Four pig-tailed macaques with a listed birth date in 2012 had been shipped out on a Wildlife Transportation Facilitators truck from New York University on April 22, 2024.

According to the report given at the June IACUC meeting, on April 29 an anonymous animal welfare concern report to UW questioned the need to transport geriatric monkeys. The AV said in the IACUC meeting that after this delivery, she had decided to suspend such shipments. A secondary issue was reported at the meeting because a new SOP implemented earlier in the year requires communication with updates on the monkeys during the transport period, but it wasn't followed.

Although strangely not discussed during the IACUC meeting, according to the statement that the university released about the incident, one of the monkeys had such poor health after arrival that euthanasia was necessary. The AWA requires that "[t]he regulated person transporting the nonhuman primates must ensure that the operator or the person accompanying the operator determines whether any of the nonhuman primates are in obvious physical distress, and obtains any veterinary care needed for the nonhuman primates at the closest available veterinary facility." 9 CFR § 3.90(a). Under this regulation, it's possible that the primate should have received veterinary care before arrival at the WaNPRC or should not have been transported at all.

Previous Water Deprivation May Have Caused Permanent Kidney Damage During the June 2024 IACUC meeting, the AV stated that in November 2022, an incident was reported in which a monkey who had been assigned to a protocol that allowed for

fluid restriction and was unintentionally denied water for more than 24 hours over a long holiday weekend. Subsequently, this monkey developed clinical issues that may be secondary to the acute water deprivation. In March 2024, this animal began refusing to eat. The veterinarian diagnosed interstitial nephritis (a kidney disorder) exacerbated by water regulation. The AV couldn't definitively say that withholding water in 2022 had directly caused the nephritis, but she did say that in her professional experience, spontaneous renal disease in young adult macaques is especially rare. PETA has documents showing the described incident, and it appears that this was a monkey on a Basso protocol. (See Enclosure 3.)

The IACUC <u>reported</u> this incident to the USDA in November 2022, which proceeded to issue a noncritical violation of 9 CFR § 3.83 on September 12, 2023, but the lack of more meaningful action failed to end this monkey's suffering.

Request: Immediate Investigation

These newly reported incidents add to the growing list of systemic problems and the toxic workplace culture at the WaNPRC. To uphold your mission to protect the health and welfare of animals in the U.S., we urge APHIS Investigative and Enforcement Services to initiate an immediate investigation into the serious, chronic, and systemic problems at the WaNPRC.

Thank you for your time and consideration.

Sincerely,

Lisa Jones-Engel, Ph.D.

Senior Science Advisor, Primate Experimentation

cc: AC.Complaints@usda.gov

Enclosures

- 1. Necropsy Report
- 2. Certificate of Veterinary Inspection
- 3. Basso Protocol Documentation

Enclosure 1

University of Washington National Primate Research Center Accession #___23-087 Submission Date 23 Aug 2023

DIAGNOSTIC LABORATORY NECROPSY REPORT

Requester MB Investigator MB Animal ID #K01081 Species Mn Requester's Phone					
Date of Death 23 Aug 23 Date of Necropsy 23 Aug 23 Time 4 pm Pathologist AB Nutritional Condition: ☐ Adequate ☐ Marginal ☐ Poor ☐ Obese Other Tests Required: ☐ Sero ☐ Micro ☐ Parasit ☐ Other ☐ Othe					
Other Diagnostic Samples					
Type of report: 🛛 Final 23 Aug 2023 🗌 Preliminary 🔲 Amended					
Clinical History: this animal was assigned to the "Neurophysiology of decision making" protocol. Gross Description: a 22 year old, 11 kg female pig tail macaque in good nutritional and post mortem condition is submitted for examination. There is a sutured linear incision on the dorsal skull. There are two approximately 1 cm incisions into the underlying skull, with gel foam inserted into the bone incisions. Upon brain removal, there is an approximately 3 cm diameter blood clot at the brain stem, oriented to the right side, and hemorrhage along the base of the brain with congested ventral cerebral vessels and submeningeal hemorrhage. The brain is placed in fixative and handed to investigator. Examination is limited to the brain.					
Gross Diagnosis(es): Inracerebral and brain stem hemorrhage, focally extensive.					
Gross Comments: hemorrhage is likely secondary to injections.					
Histological Findings: not requested.					
Final Principal Diagnosis(es):					
Histology Comments:					

Pathologist	AB	

Enclosure 2



New York Division of Animal Industry 10 B Airline Drive Albany, NY 12235 Phone: 518-457-3502

Fax: 518-485-7773

https://agriculture.ny.gov/animals/animal-import-expor

CERTIFICATE OF VETERINARY INSPECTION

CERTIFICATE NUMBER

BRAND INSPECTION NUMBER & ISSUE DATE

Contact State of Destination for Movement Requirements and Certificate Validity FOR FOREIGN SHIPMENTS (Outside United States or Leaving United States) USE FEDERAL FORM For Interstate Travel - Certificate Valid for 30 days from Inspection

ENTRY PERMIT NUMBER

ISSUE DATE

2024-04-12

24-NY-21770104

New York University 4-6 Washington Place New York, NY 10016 Phone: 332-225-6674 PIN/LID: /	CONSIGNOR, PRESEN' SHIPMENT New York University 4-6 Washington Place New York, NY 10016 Phone: 332-225-6674 PIN/LID: /	OWNER OF	DESTINATION OF Washington Nation Research Center 1705 NE Pacific S Seattle, WA 98195 Phone: 206616355 PIN/LID: /	onal Primate National t	Washing Research 1705 NE Seattle, V	ton National Primate National n Center Pacific St VA 98195 066163555	Wild P.O. Thur	RIER, TRANSPORTER Ilife Transportation Facilitators Box 527 mont, MD 21788 ne: (301) 471-3580 LID: /
SPECIES - NUMBER IN SHIPMENT Macaque () - 4 animals	PURPOSE(S) OF MOVEMENT Research	CARRIER T Climate Cor	YPE trolled Truck	HERD STATUS NU	MBER	HERD FREE FOR freeForTb	38	CURRENT STATE/AREA STATUS Tuberculosis-Free

Name: 4 | DOB: 2012-04-11 | Color: | Gender: Multiple Genders (Mixed) | Breed: Nemestrina | Head Count: 4

Official ID Types: Tattoo | IDs:

IF | QI | KJ | KI

Remarks:

OWNER / AGENT STATEMENT

The animals in this shipment are those certified to and listed on this certificate.

Signature

Date

VETERINARIAN'S SIGNATURE:

INSPECTION DATE

2024-04-12

This is a legally binding equivalent of a handwritten signature.

Mariya Morris Mariya Morris 2024-04-12 13:10:28 CDT

OFFICIAL USE ONLY

The Veterinarian issuing this certificate is accredited and has been authorized to inspect animals and issue certificates.

VETERINARIAN CERTIFICATION - I certify, as an accredited Veterinarian, that the above animals have been inspected by me and that they are not showing signs of infectious, contagious, and/or communicable disease, (except where noted). The vaccinations and results of tests are indicated on the certificate. To the best of my knowledge, the animals listed on this certificate meet the state of destination and federal interstate requirements. No further warranty is made or implied.

Mariya Morris

665 Broadway New York, NY 10016

Phone: 212-992-6048

License Number and State: National Accreditation Number: 013952 - NY 081590

Enclosure 3



CLINICAL HISTORY

Ran on 29/Mar/2023 at 11:13 am

Animal:	A21196	Age:	7.04	Project:	Basso, Michele 03 01
Sx:	M	Weight:	9.9 on 06/Mar/23	Title:	rophysiology of decision making during u
Spc:	MM	Location:	I359-A2	IACUC:	4531-04

		S-Animal is BARH and is urinating normally. Eating food well with normal stool present. AHe	
Votorinary Caso	eterinary Case Other/Unknown	Other/Unknown	S-BAR, returned to lixit, ate all chow, normal stool, and normal amount of urine in
veterinary case		pan. Readily taking treats. KWo	
		A-Returned to full water KWo	
		P-Close case and continue routine husbandry and monitoring KWo	

02/Nov/22	Information	Comments
Veterinary Case	Other/Unknown	S-Animal is bright and alert and from cageside obs seems hydrated as well. Urine in pan. Eating dry food and treats well. AHe O-CBC/Chem values reflect iStat values from previous day. Normal electrolytes with minimal elevation in creatinine KWo

01/Nov/22	Information	Comments
Veterinary Case	Other/Unknown	S-Animal drank full water bottle by PM obs. Bright and alert and taking treats readily. Evidence of urine in pan. AHe

31/Oct/22	Information				Co	mments		
Veterinary Case	Other/Unknown							
Veterinary Case	Other/Unknown	S-Animal was reported for lack of access to water for >24 hours. Animal is readily taking food treats, ate all chow. Small amount of urine and scant am dry feces in pan. After fasting, sedated to assess electrolyte abnormalities-s values. Gave ~60ml LRS IV + 120ml LRS SQ. KWo S-iStat electrolyte values WNL- creatinine minimally elevated. KWo A-Normal electrolyte balance KWo P-Continue to provide slowly increasing amounts of water over the next 48 Continue full water for remainder of week. KWo				of urine and scant amount of colyte abnormalities-see iStat S SQ. KWo mally elevated. KWo KWo rater over the next 48 hours.		
Sub Case	Other/Unknown				[v	ia WF]		
Administration of medication	MM							
Administration of medication								
Blood Draw	MM							
CBC					W	NL KW		
Physical Exam		[via V	WF]Mild tartar		moved wit			cal contents palpated in GI.
Physical examination	MM							
Serum Chemistry				Elevated	creatinine	e. See S	OAP note	es. KW
Serum Chemistry					[via	WF] iSta	t	
Treatment and/or								
observation								
Procedure	Drug	Start	End	Dose	Unit	Rt	Freq	Administered By
Administration of medication	Cerenia (maropitant citrate)	31/Oct/22	10/31/22	11	mg	SQ	ONC	ММ
Administration of medication	Ketamine HCI	31/Oct/22		110	mg	IM		MM

13/Oct/22	Information	Comments
Weight	11.2	

12/Oct/22	Information	Comments
Behavioral Monitoring		

11/Oct/22	Information	Comments
Behavior Observations		

03/Oct/22	Information	Comments
Weight	11.2	

15/Sep/22	Information	Comments
Behavioral Monitoring		