AN INTERNATIONAL ORGANIZATION DEDICATED TO PROTECTING THE RIGHTS OF ALL ANIMALS

July 2, 2024

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

Via e-mail: <u>Roxanne.C.Mullaney@usda.gov</u>

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



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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 <u>the statement</u> 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: <u>AC.Complaints@usda.gov</u>

Enclosures

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

Enclosure 1

Accession #<u>23-087</u> Submission Date <u>23 Aug 2023</u>

University of Washington National Primate Research Center

DIAGNOSTIC LABORATORY NECROPSY REPORT

Requester SpeciesMn	<u>MB</u> Investigator <u>MB</u> Animal ID # <u>K01081</u> Requester's Phone
Date of Death 23 Aug 23	3 Date of Necropsy 23 Aug 23 Time 4 pm Pathologist AB
Nutritional Condition:	Adequate Arginal Poor Obese
Other Tests Required:	Sero Micro Parasit Other
Other Diagnostic Sample	es

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

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Enclosure 3

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