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April 1, 2021

To whom it may concern:

Re: Appeal of Inspection Report No. 2016090000524464

On January 26, 2021 Diane Forbes, Veterinary Medical Officer, USDA, APHIS, Animal Care and Michael Schnell, Veterinary Medical Officer, USDA, APHIS, Animal Care (collectively, "Animal Care Officials"), conducted an inspection of our institution, University of Washington National Primate Center ("University of Washington"). We thank VMO Forbes and VMO Schnell for their time and service, and respectfully file this Appeal of Inspection Report No. 2016090000524464 ("the Report"). After an in depth review of the facts surrounding the purported noncompliant items on the Report, we provide the following information as to why University of Washington should not have received any noncompliant citation on the Report pursuant to then-governing USDA APHIS Guidance Documents, APHIS Tech Note "Incentives for Identifying, Reporting, Correcting, and Preventing Noncompliance with the Animal Welfare Act" dated May 2018 ("Incentive Reporting"), and Animal Welfare Inspection Guide revised March 2020 ("the Guide") and OMB guidance, "Implementation of Section 6 of Executive Order 13924" ("M-20-31"). The inspection and the Report must comply with the law and guidance documents which were governing law at that time the inspection began, in order to avoid violations of the Due Process Clauses of the Constitution of the United States.¹

Before describing in detail why University of Washington believes that each of the citations on the Report should have qualified under the Incentive Reporting, University of Washington would like to express its concern about the nature and length of the January 26 inspection. This inspection, conducted remotely, required University of Washington to provide voluminous records over the course of 16 days, in many cases providing the same documents multiple times, compared with a typical, in person inspection which lasts three days. The draft inspection report was provided to University of Washington 41 days later, which appears to violate Animal Care guidance requiring the finalized inspection report to be completed, delivered or sent to the registrant "**within 5 business days of the date of the inspection.**" Animal Care Inspection Guide, 3.3.1 (emphasis in original). Finally, it appears that the inspection was not conducted pursuant to guidance "SOP for Remote Focused Research Facility Inspections" since it was not limited to document review, and not designated Focused Inspection. While University of Washington fully cooperated with Animal Care Officials during the inspection, it believes

¹ The Incentive Reporting guidance was not revoked until February 12, 2021, and during the Inspection Animal Care Officials informed University of Washington that it was revoked as of April 2021. The Guide was revised on January 26, 2021, but stakeholders were not informed of the revision until February 12, 2021. OMB guidance M-20-31 was withdrawn on February 26, 2021.

that the nature and length of the inspection was not reasonable nor in compliance with Animal Care guidance.

Additionally, University of Washington is concerned that Animal Care Officials rejected the robust, IACUC-approved corrective action implemented in a timely manner, and well before the January 26 inspection related to Citation 2 and Citation 3, and refused to clarify why such corrective actions were insufficient. This appears to violate Animal Welfare Guidance, which directs inspectors not to mandate how a noncompliant item is to be corrected. Animal Welfare Inspection Guide, 2.4.4 (4). By refusing to acknowledge that the IACUC-approved corrective actions were sufficient, they were essentially mandating an undisclosed alternate solution.

Finally, Animal Care Officials were required to “apply. . .the rule of lenity in administrative investigations, enforcement actions, and adjudication by reading genuine statutory or regulatory ambiguities related to administrative violations and penalties in favor of the targeted party in enforcement . . .[and to] establish policies of enforcement discretion that decline enforcement or the imposition of a penalty, as appropriate, in the course of enforcement when the agency determines that the regulated party attempted in good faith to comply with the law” during this inspection. See M-20-31 (a), (f).

For these reasons, and as further described below, University of Washington appeals each of the non-compliance citations on the Report.

Citation No. 1 2.33(b)(3) Attending Veterinarian and Adequate Veterinary Care.

This noncompliant citation should not have been issued on the Report, because the incident was promptly reported to VMO Forbes within 24 hours of the incident, based on then-binding USDA guidance, stating:

Problems Addressed by the Facility before Inspection

If you learn during the course of an inspection that the facility identified and corrected a problem in the past, a citation will not be written if all of the following are true:

- The licensee/registrant found and corrected the problem in a timely manner
- The licensee/registrant took steps to prevent the problem from recurring
- There is not an ongoing pattern of noncompliances, and
- There were no serious animal welfare impacts associated with the current problem.

See Animal Welfare Inspection Guide, 9/2013, at 2-4.

The incident was found and corrected in a timely manner by University of Washington. This was identified as a husbandry personnel error who failed to comply with existing husbandry protocols. University of Washington reported that as part of its corrective action, HR was investigating to determine any personnel actions to taken, in addition to retraining which is required pursuant to SOP. Additionally, as reported to OLAW and USDA, “[t]he AV mentioned that there is currently a discussion to [potentially] incorporate electronic room logs that could be checked by supervisory staff even remotely rather than using paper room logs” which are required pursuant to existing approved SOP’s. University of Washington February 18, 2021 IACUC Meeting Minutes. This incident is not an ongoing pattern of noncompliances, particularly if this incident were properly cited pursuant to 2.32(a) or 2.32(c)(1)(2)

“Personnel qualifications.” There is no evidence that the incident was recurrent; and the animals all appeared healthy.

This is also consistent with the governing Incentive Reporting tech note, which should have resulted in no citations because, as a non-critical compliance:

- University of Washington identified the potential noncompliance outside of the inspection process and within 24 hours reported the incident to Animal Care Officials at the start of the January 26 inspection; and
- University of Washington timely discovered the alleged noncompliance using its own compliance monitoring program; and
- University of Washington immediately took appropriate corrective action and established measures to prevent recurrence, as indicated in the Report; and

University of Washington additionally objects to the classification of the citation as 2.33(b)(3) and requests a correction to a citation to 2.32(a) or 2.32(c)(1), since veterinary care was not inadequately provided in any SOP or during the incident.

Finally, University of Washington questions the legal basis for the Animal Care Officials’ determination that they were required to include Citation No. 1 on the Report because of the number of other citations in the Report. Neither the AWA, related regulations nor Incentive Reporting guidance provide any basis for this statement, and Citation No. 1 should be removed from the Report.

Citation No. 2 2.38(f)(1) Miscellaneous (designated as Critical)

This noncompliant citation should not have been issued on the Report, because the incident was promptly reported to Animal Care Officials within five days after the incident, based on then-binding USDA guidance for the following reasons:

The incident was found and corrected in a timely manner by University of Washington. This was identified as a husbandry personnel error, where personnel failed to comply with existing husbandry protocols that provide for the humane care of animals. The NHP at issue in this incident was observed daily as required by AWA regulations. University of Washington reported that it immediately implemented its corrective action, including: the addition of water bottles to runs that will be available to animals in those runs at all times, and an investigation by HR to determine any personnel actions to be taken, for those employees that did not follow procedure and confirm the location of the animal in addition to retraining which is required pursuant to SOP. It is a responsibility of the employee to confirm the location of each animal during their shift.

Additional corrective action were implemented well before the inspection initiated on January 26, 2021, including: long term plans include the incorporation of electronic tablets and electronic room logs that will be checked by supervisory staff remotely, a plan expected to be implemented by the end of 2021; plans beginning summer 2021 to renovate space in the Health Sciences Building to build new modernized compounds where animals will be relocated to Campus. The compounds will have capabilities to separate animals for cleaning and treatment that are within the room and easily visible. Also, as part of its ever-evolving plans to provide for care of its animals, on January 26, 2021, University of Washington added a verification of animal count to the duties of the veterinary technician at the end of the day and this has been added to the check sheet. Based on this there are at least three separate individuals that verify that animals are in their correct locations daily—a morning AT, the afternoon AT

and the Veterinary Technician. The morning AT and the afternoon AT are different individuals unless the UW is operating under emergency procedures.

Furthermore, Citation No. 2 should have been classified as qualified under APHIS's Incentives Reporting for the following reasons:

- University of Washington had no repeat or critical noncompliance on any inspection report for the relevant approved site during the preceding 12 months; and
- University of Washington timely discovered the alleged noncompliance using its own compliance monitoring program; and
- University of Washington had not voluntarily reported a noncompliance that falls within the same section and subsection of the AWA regulations and standards during the preceding 24 months for the relevant approved site; and
- University of Washington immediately took appropriate corrective action and established measures to prevent recurrence; and
- University of Washington promptly reported the incident to its Animal Care inspector five days after the incident and cooperated with the inspector as she reviewed the incident.

During the Exit Interview, VMO Forbes and VMO Schnell impermissibly rejected University of Washington's IACUC approved corrective actions and did not have an explanation as to why the corrective actions were insufficient when asked. No regulations provide a basis for this rejection, nor is there any identification of how these corrective actions violate any AWA statute or regulation. But not for this rejection, the incident would not have been documented as a citation on the Report.

Citation No. 3 3.80(a)(2)(iii) Primary Enclosures (designated as Critical)

First, University of Washington has concluded, after full and comprehensive review of all of the evidence related to this incident, that there were no violations of any University of Washington IACUC SOP or any other governing SOP. These include SOP's for socializing animals, enclosure construction, checking enclosure and lock integrity daily, and emergency response. As such, the incident should not have been classified as a noncompliance—this was a case where there was an unexpected enclosure failure at the connection between two enclosures joined for socialization.

In order to enrich animals' environment, University of Washington socializes and group houses animals pursuant to existing IACUC-approved SOP's which requires reliance on the use of interconnected enclosures. University of Washington has utilized these connected enclosures without an incident of this nature since 2012. When animals are put into new social groups, they are monitored frequently in-person and remotely via live camera feed to identify any problematic behavior. Staff regularly checks all enclosures to ensure that they are properly attached and the animals are safe in their enclosures.

It is also imperative to amend the reporting of this incident, which was mistakenly based on speculation, not fact. Specifically, there was no witness to the actual incident in person or via video. The socially co-housed male and female NHP were observed in their enclosure twice on April 9, 2020, the day before the incident. The enclosure and locks were intact during the pm observation. When first observed on the morning of April 10, 2020, there were two damaged locks on the floor of the room in which the enclosure was located and the enclosure itself was damaged. The socially co-housed male and female NHP were observed in the room where other NHP's were housed in separate enclosures in

the room. Veterinary response protocols were implemented to examine and treat the NHP's that exhibited minor injuries, and the male was moved to another enclosure and housed without his social partner until a new enclosure with additional security and locks was constructed.

Additional IACUC-approved corrective actions included:

Adding additional locks and reinforcements at the interlocking mechanisms of the adjoining enclosures and adding additional locks to the two (2) other connectors on the front part of the enclosure resulting in three (3) separate locations on the front enclosure with locks. An additional three (3) connectors were added to the back of the enclosure where locks can be placed, so that the 2 enclosures are connected/locked together by three (3) areas in the front and three (3) areas in the back.

During the Exit Interview, VMO Forbes and VMO Schnell impermissibly rejected University of Washington's IACUC approved corrective actions and did not have any explanation as to why the corrective actions were insufficient when asked. No regulations provide a basis for this rejection, nor is there any identification of how these corrective actions violate any AWA statute or regulation. But not for this rejection, the incident would not have been documented as a citation on the Report.

Even if Animal Care identified a noncompliance supported by credible evidence, the incident qualifies under the Incentives Tech Note because of the following:

- University of Washington had no repeat or critical noncompliance on any inspection report for the relevant approved site during the preceding 12 months; and
- University of Washington timely discovered the alleged noncompliance using its own compliance monitoring program; and
- University of Washington had not voluntarily reported a noncompliance that falls within the same section and subsection of the AWA regulations and standards during the preceding 24 months for the relevant approved site; and
- University of Washington immediately took appropriate corrective action and established measures to prevent recurrence; and
- University of Washington promptly reported the incident to its Animal Care inspector four days after the incident and cooperated with the inspector as she reviewed the incident.

Citation No. 4 2.31 (e)(3) IACUC (designated as Critical)

This citation should not have been included on the Report, because the incident was first reported to Animal Care Officials on September 18, 2019, as soon as it was identified as a potential noncompliance by University of Washington. Pursuant to Incentive Reporting, it was discussed during the subsequent inspection on December 4, 2019, where no noncompliant citations were reported. Animal Care officials, during that inspection did not reserve their right to continue a review of this incident. The inclusion of a citation on the Report appears to violate the guidance which prohibits the addition of a "Direct, Critical or Reseat designation or an additional citation to an Inspection Report after it has been given to the . . . registrant." Animal Care Inspection Guide, 2.16.2. Such guidance would be rendered moot if an inspector were able to revisit the same incident, absent any new facts, at a subsequent inspection and then identify it as a citation.

It also violates the then-governing federal guidance that states "an agency should have only one bite at the apple to investigate and seek enforcement against a regulated entity for a static factual

predicate that is not a continuing or expanding violation.” M-20-31 (b). Animal Care Officials were provided with all relevant information regarding this incident during the December 2019 inspection, including the relevant IACUC meeting minutes describing same. Additional discussion at a subsequent IACUC meeting in November 2020 contained no additional relevant information regarding the welfare of the animals that had not been previously disclosed.

Additionally, this incident also falls within the Incentive Reporting qualifications to exclude it from being classified as a citation for the following reasons:

- University of Washington had no repeat or critical noncompliance on any inspection report for the relevant approved site during the preceding 12 months; and
- University of Washington timely discovered the alleged noncompliance using its own compliance monitoring program; and
- University of Washington had not voluntarily reported a noncompliance that falls within the same section and subsection of the AWA regulations and standards during the preceding 24 months for the relevant approved site; and
- University of Washington immediately took appropriate corrective action and established measures to prevent recurrence, prior to inspection; and
- University of Washington promptly reported the incident to its Animal Care inspector as soon as it was identified as a potential noncompliance and cooperated with the inspector as she reviewed the incident. This incident was initially reported to University of Washington’s Animal Care inspector 496 days prior to the Report.

We appreciate your consideration of this appeal to the four (4) citation on the Report and are available to provide further information as necessary.

Sincerely,

(b) (6), (b) (7)(C)

(b) (6), (b) (7)(C) for Research Administration and Integrity

Attachments:

- A. OMB Memo
- B. Incentive TechNote
- C. SOP for Remote Focused Research Facility Inspections
- D. Acting Animal Welfare Guide (relevant section, before removal of incentive section)
- E. Excerpt of Minutes
- F. University of Washington Corrective action letter