

May 10, 2022

Brent Morse, DVM Director Division of Compliance Oversight Office of Laboratory Animal Welfare

Via e-mail: morseb@mail.nih.gov

Dear Dr. Morse:

I am writing on behalf of People for the Ethical Treatment of Animals to request that the Office of Laboratory Animal Welfare (OLAW) investigate concerns related to the treatment of monkeys held in colonies managed by the University of Washington (UW; PHS Assurance ID D16-00292, A3464-01) and the affiliated Washington National Primate Research Center (WaNPRC). It appears that the treatment of monkeys—at WaNPRC's sites in Seattle, Wash. and Mesa, Ariz.; and held in WaNPRC's Specific Pathogen Free (SPF) colony at the New Iberia Research Center (NIRC), which is part of the University of Louisiana at Lafayette (ULL; PHS Assurance ID D16-00016, A3029-01)—failed to comply with the Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy) and the Guide for the Care and Use of Laboratory Animals (the *Guide*).

In response to a Washington public records request submitted to the University of Washington in October 2021, requesting all WaNPRC final necropsy and pathology reports for primates for a period of four years, PETA received nearly 800 necropsy reports. A review of these documents revealed that husbandry and veterinary staff failed to act in accordance with current established veterinary procedures or even demonstrate a basic level of competence; pathologists failed to adequately pursue diagnoses in experimental and colony animals; and investigators failed to probe underlying, undetected, and/or unintended infections which could impact the scientific integrity of the experimental model and have broader repercussions for the research and breeding colonies. It appears to us that the practices evident in the necropsy reports may constitute noncompliance with PHS Policy and the *Guide*, including:

- 1. Failure to maintain an adequate veterinary care program;
- 2. Failure to ensure that monkeys are adequately fed; and
- 3. Failure to ensure that only compatible monkeys are caged together.

<sup>1</sup>Curiously, the NIRC site is not included in UW's current PHS Assurance, or the Assurance that expired in December 2020, even though WaNPRC received NIH funding through U42 and P51 grants to maintain an SPF colony of pigtailed macaques at that location from at least 2009 to 2020. As you know, NIH's guidance is explicit that: "PHS Policy applicability is not limited to research" and includes "animals used as ... breeding stock." We recognize that NIH's oversight of the care and maintenance of WaNPRC's colony of monkeys at NIRC could be carried out via the PHS Assurance maintained by ULL.

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The *Guide* advises that an "adequate veterinary care program consists of assessment of animal well-being and effective management of" numerous considerations including "preventative medicine," "clinical disease, disability, or related health issues," "surgery and perioperative care," "pain and distress," and "euthanasia."

# In particular, the *Guide* states:

Disease prevention is an essential component of comprehensive veterinary medical care ... [which] enhances the research value of animals by maintaining health animals and minimizing nonprotocol sources of variation associated with disease and inapparent infection, thus minimizing animal waste and potential effects on well-being.

### Also:

Animal biosecurity refers to all measures taken to identify, contain, prevent, and eradicate known or unknown infections that may cause clinical disease or alter physiologic and behavioral responses or otherwise make the animals unsuitable for research. Animal biosecurity practices should be applied to all species, but they are most important when housing large numbers of animals in intensive housing conditions ... Limiting exposure of animals to infectious disease agents requires consideration of physical plant layout and operational practices.

# The Guide further elucidates:

All animals should be observed for signs of illness, injury, or abnormal behavior by a person trained to recognize such signs ... Appropriate procedures should be in place for disease surveillance and diagnosis. Unexpected deaths and signs of illness, distress, or other deviations from normal in animals should be reported promptly and investigated, as necessary, to ensure appropriate and timely delivery of veterinary medical care ... Procedures for disease prevention, diagnosis, and therapy should be those currently accepted in veterinary and laboratory animal practice ... Access to diagnostic laboratory services facilitates veterinary medical care and can include gross and microscopic pathology, hematology, microbiology, parasitology, clinical chemistry, molecular diagnostics, and serology.

## On the issue of surgery, the *Guide* advises:

Successful surgical outcomes require appropriate attention to presurgical planning, personnel training, anesthesia, aseptic and surgical technique, assessment of animal wellbeing, appropriate use of analgesics, and animal physiologic status during all phases of a protocol involving surgery and postoperative care ... Researchers conducting surgical procedures must have appropriate training to ensure that good surgical technique is practiced—that is, asepsis, gentle tissue handling, minimal dissection of tissue, appropriate use of instruments, effective hemostasis, and correct use of suture materials and patterns ... An important component of postsurgical care is observation of the animal and intervention as necessary during recovery from anesthesia and surgery.

However, WaNPRC has consistently failed to ensure that the environment that their infants are born into is safe and healthy. Infant pigtailed macaques born in WaNPRC's SPF colonies suffered with poor body condition, diarrhea, lethargy, dehydration and ultimately death. Despite the well-known consequences that diarrhea and diseases of the gastrointestinal tract present for animal health and

scientific rigor,<sup>2</sup> there is no indication that WaNPRC took meaningful measures to prevent, control or diagnose the etiology of illnesses that caused severe suffering and death among the most vulnerable monkeys in the WaNPRC colonies. A recent award-winning expose of the WaNPRC breeding facility in Mesa documented 47 pigtailed macaque deaths, including multiple infants in this facility. <sup>3</sup>

# A. Pathology reports attribute 25 infant monkey deaths to starvation, diarrhea, hypoglycemia, pneumonia and/or failure to nurse

- 1. On January 3, 2018, at WaNPRC's SPF colony at NIRC, a 27-day-old female pigtailed macaque identified as Z17324 was found dead with poor body condition, malnourished, and possibly immunocompromised. The necropsy report stated that abscesses in her colon were likely bacterial in origin and could be attributed to *Shigella, Campylobacter, Salmonella, Yersinia sp* and others. However, no definitive identification of an etiologic agent was undertaken.<sup>4</sup>
- 2. On June 15, 2018, at WaNPRC's Mesa facility, a five-day-old male pigtailed macaque identified as Z18123 and with a body condition score of 1.5/5 was found dead in his mother's arms. The mother was housed in a breeding group compound that had been receiving Fluconazole treatments since 2016 as part of an effort to mitigate Coccidioidomycosis infections that were rampaging through the colony. Necropsy report states that the infant died due to "severe ... pneumonia" "that almost certainly was of bacterial origin." No definitive identification of an etiologic agent was made.<sup>5</sup>
- 3. On August 23, 2018, at WaNPRC's SPF colony at NIRC, a six-day-old newborn male pigtailed macaque identified as Z18160 was noted to be lethargic; clinical notes on the necropsy do not indicate whether treatment was offered. The infant was found dead the next day. The suggested cause of death was "inadequate nursing." No attempt at identifying an etiological agent was made.<sup>6</sup>
- 4. On August 24, 2018, at WaNPRC's SPF colony at NIRC, a two-day-old newborn male pigtailed macaque identified as Z18146 was noted to be dehydrated. The infant was found dead the next day. The suggested cause of death was "hypoglycemia from inadequate nursing." The newborn's body was severely autolyzed, precluding a comprehensive necropsy.<sup>7</sup>
- 5. On November 7, 2018, at NIRC, a female pigtailed macaque newborn identified as Z18205 was abandoned by her mother and moved to the nursery. An attempted reintroduction failed and the infant was returned to the nursery. By day 4 the infant, presumably being maintained in the nursery, was dead. The cause of death was noted as inanition. No definitive identification of an etiologic agent was made.<sup>8</sup>

<sup>&</sup>lt;sup>2</sup> Johnson AL, Keesler RI, Lewis AD, Reader JR, Laing ST. Common and Not-So-Common Pathologic Findings of the Gastrointestinal Tract of Rhesus and Cynomolgus Macaques [published online ahead of print, 2022 Apr 1]. *Toxicol Pathol*. 2022;1926233221084634. doi:10.1177/01926233221084634

<sup>&</sup>lt;sup>3</sup> Arizona Republic wins National Headliner Award for monkey farm series (azcentral.com)

<sup>&</sup>lt;sup>4</sup> Ex. 1

<sup>&</sup>lt;sup>5</sup> Ex. 2

<sup>&</sup>lt;sup>6</sup> Ex. 3

<sup>&</sup>lt;sup>7</sup> Ex. 4

<sup>&</sup>lt;sup>8</sup> Ex. 5

- 6. On November 29, 2018, at WaNPRC's Mesa facility, a less than one month-old infant pigtailed macaque identified as Z18197 was found dead in the nursery. Two days after birth the infant had been removed from his mother and found to be positive for *Enteropathogenic E.coli*. Over the next three weeks, the infant was shuffled back and forth between the nursery and his mother as his physical condition fluctuated. On November 29, 2018, he was again removed from his mother and placed in a nursery cage with a self-feeding bottle. He was found dead that evening after consuming 62 ml of formula. The necropsy report concluded, "Proximal cause of death was acute, severe aspiration pneumonia," and histology also found severe pancreatitis, likely from "a past adenoviral infection." No definitive identification of an etiologic agent was made. 9
- 7. On January 2, 2019, at WaNPRC's SPF colony at NIRC, a six-day-old male pigtailed macaque identified as Z18230 was found dead in the SPF enclosure. The necropsy report identified pyogranulomatous colitis (severe inflammatory bowel disease) and inanition. The differential diagnosis included *Shigella*, *Campylobacter*, *Salmonella*, *Yersinia sp* and others as possible sources, but no definitive identification of an etiologic agent was made. <sup>10</sup>
- 8. On January 5, 2019, at WaNPRC's SPF colony at NIRC, a three-week-old male pigtailed macaque identified as Z18226 was found dead in the WaNPRC SPF enclosure. The necropsy report suggests that inanition and hypoglycemia led to the infant's death, and the presence of hypoplastic lymph nodes was indicative of developing secondary immunosuppression. The infant's body was severely autolyzed, precluding a histological evaluation of the gastrointestinal tract.<sup>11</sup>
- 9. On January 14, 2019, at WaNPRC's SPF colony at NIRC, a newborn male pigtailed macaque identified as Z19030 was found dead in the SPF enclosure. No cause of death was provided for this monkey who lived for less than 24 hours—although the necropsy report simply speculated that the infant's large size suggested a difficult delivery that could "result in a weak infant unable to suckle properly." 12
- 10. On February 24, 2019, at WaNPRC's SPF colony at NIRC, a newborn infant pigtailed macaque identified as Z18231 was found dead in the SPF colony. The necropsy report speculated, "Hypoglycemia from inadequate nursing is a possible cause of demise and is common in this age group." However, no definitive cause of death was provided for this 900-gram neonate.<sup>13</sup>
- 11. On February 26, 2019, at WaNPRC's Mesa facility, a 2.5-week-old infant pigtailed macaque identified as Z19049 was found dead in the enclosure with multiple wounds. The necropsy did not definitively determine whether the wounding was pre- or post-mortem. The histological findings at necropsy included necrotizing pneumonia due to "acute aspiration pneumonia" associated with "foreign material and mixed bacteria." However, no definitive identification of an etiologic agent was made. 14
- 12. On May 5, 2019, at WaNPRC's Mesa facility, a one-week-old male pigtailed macaque identified as Z19106 was found dead in a group enclosure. The clinical history notes that three days prior to the infant's death he and his mother were examined. The infant was noted to be nursing and gripping well. The mother's exam revealed "no evidence of dehydration and excellent milk production." On the day of the exam (5/2) the infant was

<sup>10</sup> Ex. 7

<sup>&</sup>lt;sup>9</sup> Ex. 6

<sup>&</sup>lt;sup>11</sup> Ex. 8

<sup>&</sup>lt;sup>12</sup> Ex. 9

<sup>&</sup>lt;sup>13</sup> Ex. 10

<sup>&</sup>lt;sup>14</sup> Ex. 11

treated with SQ fluids to correct an estimated 3% dehydration. Mother and infant were observed over the next two days (5/3 and 5/4). The infant was nursing and the clinical history notes that both mother and infant "appeared normal during treatments for that social group". On the morning of May 5<sup>th</sup> the infant was found dead in the enclosure and the mother was noted as lethargic with sunken eyes and had diarrhea. A fecal from the mother was sent for Biofire screening but results were not noted in the necropsy report. The necropsy report concluded that gross and histological findings from the infant were "consistent with developing inanition" and cause of death for the infant was listed as "hypoglycemia and dehydration, due to inadequate suckling." Inanition is not an acute process—but this infant went from "appeared normal" to dead in less than 12 hours. There is an apparent lack of diagnostic rigor, particularly given that this infant was part of a group that was "receiving treatment" for an unspecified condition and the infant's mother experienced a sudden decompensation. <sup>15</sup>

- 13. On July 16, 2019, at WaNPRC's SPF colony at NIRC, a one-week-old male pigtailed macaque identified as Z19187 was found lethargic in the enclosure. He was removed to the nursery for supportive care, but was found dead the next day. The necropsy report indicated severe, pyogranulomatous infiltrates in the infant's lungs. Coccobacilli are noted, but no definitive identification of an etiologic agent was made. <sup>16</sup>
- 14. On August 4, 2019, at WaNPRC's SPF colony at NIRC, a three-day-old male pigtailed macaque identified as Z19202 was found dead. The necropsy report determined that the infant's lungs had "severe, multifocal and coalescing, effacing suppurative infiltrate in all airways." Coccobacilli bacteria were also noted, but not typed. Death was attributed to "pneumonia that was of bacterial origin." <sup>17</sup>
- 15. On August 27, 2019, at WaNPRC's SPF colony at NIRC, a two-day-old male pigtailed macaque identified as Z19214 was abandoned by his mother. Staff removed him to the nursery, but he died during the night. The necropsy report documented "umbilical abscess with rod to mixed bacteria." However, the cause of death was inconclusive with "hypoglycemia secondary to abandonment [being] suspect." No definitive identification of an etiologic agent was made. 18
- 16. On October 22, 2019, at WaNPRC's Mesa facility, a four-day-old infant pigtailed macaque identified as Z19260 was moved with his mother from their breeding group enclosure to a single cage for monitoring after the infant was noted to be thin. Eight days later on October 30, 2019, the infant's body condition score was 1/5, he had superficial wounds, fecal staining, and was 10% dehydrated. The infant was moved to the nursery, but his condition deteriorated and he died the next day. The necropsy report indicated that the infant died due to typhlocolitis. The differential diagnosis included *Shigella*, *Campylobacter*, *Salmonella*, *Yersinia sp* and others as possible sources, but no definitive identification of an etiologic agent was made. <sup>19</sup>
- 17. On February 9, 2020, at WaNPRC's SPF colony at NIRC, a newborn (sex unknown) pigtailed macaque identified as Z20022 was found dead. Necropsy significant findings suggest inanition with evidence of immunosuppression that likely was secondary to inanition. No attempt at identifying an etiological agent was made.<sup>20</sup>

<sup>16</sup> Ex. 13

<sup>&</sup>lt;sup>15</sup> Ex. 12

<sup>&</sup>lt;sup>17</sup> Ex. 14

<sup>&</sup>lt;sup>18</sup> Ex. 15

<sup>&</sup>lt;sup>19</sup> Ex. 16

<sup>&</sup>lt;sup>20</sup> Ex. 17

- 18. On December 31, 2020, at WaNPRC's Mesa facility, a 1.5-month-old female pigtailed macaque identified as Z20186 was noted with chronic weight loss, dehydration and diarrhea; she died following cardiac arrest. At death her body condition score was 1.5/5. Necropsy notes that the proximal cause of death was "likely fluid and electrolyte loss and toxemia/septicemia due to the severe colitis." The differential diagnosis included *Shigella*, *Campylobacter*, *Salmonella*, *Yersinia sp* and others as possible sources, but no definitive identification of an etiologic agent was made.<sup>21</sup>
- 19. On January 21, 2021, at WaNPRC's Mesa facility, 3-day-old female pigtailed macaque identified as Z21003, was found dead in her mother's arms. Gross necropsy notes: "Suspect cause of death was due to failure to nurse and resultant hypoglycemia. Dam is doing well. **Tissues/organs will not be evaluated histologically unless the dam develops clinical signs.**" [Emphasis added.] There is an apparent lack of diagnostic rigor. No attempt at identifying an etiological agent was made.<sup>22</sup>
- 20. On May 11, 2021, at WaNPRC's Mesa facility, a 1-month-old female pigtailed macaque identified Z20158 who was noted to have a history of difficulty breathing was euthanized following significant decompensation and seizure. Necropsy notes: "Severe, multifocal, suppurative to pyogranulomatous pneumonia" "of probable bacterial etiology" and moderate, multifocal, suppurative colitis, also of "likely bacterial" origin. The differential diagnosis included *Streptococcus pneumoniae* or other agents such as *Klebsiella pneumoniae* as possible sources of for the severe pneumonia and *Shigella, Campylobacter, Salmonella, Yersinia sp* and others as possible sources for the colitis, but no definitive identification of an etiologic agent was made.<sup>23</sup>
- 21. On May 27, 2021, at WaNPRC's Mesa facility, an infant male pigtailed macaque, identified as Z21094, was found dead in a nursery isolette. The infant had been delivered by C-section less than 48 hours earlier and was rejected by his mother and surrogates. Necropsy notes severe, multifocal, fibrinosuppurative to pyogranulomatous pneumonia and vasculitis which the pathologists attribute to bacterial sepsis. No definitive identification of an etiologic agent was made.<sup>24</sup>
- 22. On June 2, 2021, at WaNPRC's Mesa facility, 20-day-old female pigtailed macaque identified as Z21088, was observed seizing in a breeding group enclosure in which she was held with her mother. The infant was removed and treatment was attempted following the observation of severe abdominal bloat and foul-smelling, liquid feces. The infant was euthanized that evening after another seizure was observed. Necropsy noted pneumonia, colonic crypt abscesses and severe diarrhea. The cause of the seizures could not be determined histologically. No definitive identification of an etiologic agent was made.<sup>25</sup>
- 23. On June 28, 2021, at WaNPRC's Mesa facility, a newborn male pigtailed infant less than 12 hours old and identified as Z21109 was discovered dead in the enclosure with his mother. External injuries to the infant's head, chest, and genitals were noted on gross exam and hypothesized to have occurred after death. The pathologist concluded: "Lack of lesions in concert with history and gross findings suggest hypoglycemia (secondary to inadequate suckling) as cause of demise." in this neonate who was less than 12 hours old. 26

<sup>22</sup> Ex. 19

<sup>&</sup>lt;sup>21</sup> Ex. 18

<sup>&</sup>lt;sup>23</sup> Ex. 20

<sup>&</sup>lt;sup>24</sup> Ex. 21

<sup>&</sup>lt;sup>25</sup> Ex. 22

<sup>&</sup>lt;sup>26</sup> Ex. 23

- 24. On July 1, 2021, at WaNPRC's Mesa facility, 5-day-old female pigtailed macaque identified as Z21108, with poor maternal handling and care was moved to the nursery after developing diarrhea and dehydration. In the nursery the animal deteriorated rapidly. Necropsy notes pyogranulomatous pneumonia "of probable bacterial etiology" and pyogranulomatous colitis. The differential diagnosis included *Shigella, Campylobacter, Salmonella, Yersinia sp* and others as possible sources, but no definitive identification of an etiologic agent was made. **This was the fifth dead infant at WaNPRC's Mesa facility within seven weeks.**<sup>27</sup>
- 25. On August 17, 2021, at WaNPRC's Mesa facility, a newborn male pigtailed macaque identified as Z21145, who was less than 12 hours old was found dead; listed cause of death was hypoglycemia. No attempt at identifying an etiological agent was made. Inanition is not an acute process. There is an apparent lack of diagnostic rigor, particularly given that during the last three months multiple infants in this colony had died unexpectedly.<sup>28</sup>

These 25 incidents of infant pigtailed macaques found dead in enclosures, cages and/or nurseries detail a pattern of WaNPRC veterinarians/pathologists failing to determine what etiological agents and/or environmental factors were contributing to the wasting, inanition, diarrhea and death ravaging the WaNPRC SPF pigtailed macaque colonies. The frequent copy and paste diagnoses of "inanition, dehydration and hypoglycemia from inadequate nursing" and infections which "were probably bacterial in origin," with common agents including *Shigella, Campylobacter, Salmonella, Yersinia* sp and others represents a lack of diagnostic rigor and common sense. In particular, infants less than 24 hours old are unlikely to die from dehydration, hypoglycemia and inanition UNLESS there is an underlying condition that prevented the infant from nursing.

Coccidiodiomycosis has been detected in WaNPRC monkeys.<sup>29</sup> Additionally, in a recent communication to OLAW, UW claimed that monkeys at WaNPRC's Mesa facility routinely undergo screening for Coccidioides and if its research or breeding monkeys "show clinical signs of a possible infectious disease, they may be tested for Campylobacter, Shigella, Salmonella, Cryptosporidium and Vibrio by multiplex PCR or culture and treated as appropriate."30 That WaNPRC acknowledges the presence of pathogens in its colonies and in some of the necropsies above either explicitly or implicitly indicate that Coccidiodiomycosis is impacting the infants' dam—see #2 (Z18123: "This particular group has been on fluconazole treated feed since March 2016"); #12 (Z19106: "The dam and infant appeared normal during treatments for that social group on 5/3/19 and 5/4/19"); and #19 (Z21003: "Tissues/organs will not be evaluated histologically unless the dam develops clinical signs")—vet fail to conduct comprehensive necropsies/histopatholgies, PCR, cultures, and/or strain typing which would allow them to make a definitive identification of the etiologic agent is inconceivable. This is not only a failure to ensure an adequate veterinary care program; the failure to identify and control these infections increases the risk to public health and further undermines the reliability and utility of these monkeys as biomedical models—in further noncompliance with PHS Policy and the Guide.

Coccidioides, Shigella, Campylobacter, Salmonella, and Yersinia sp were not the only infectious agents that were circulating in the WaNPRC colonies during the first 7 months of 2021 during which multiple infants died. On June 20, 2021, at WaNPRC's Mesa facility, a 14 year-old female

<sup>28</sup> Ex. 25

<sup>&</sup>lt;sup>27</sup> Ex. 24

<sup>&</sup>lt;sup>29</sup> Ex. 26

<sup>&</sup>lt;sup>30</sup> Ex. 27

pigtailed macaque, J06251, was found collapsed in her enclosure; emergency treatment failed to improve her condition and she was euthanized.<sup>31</sup> Gross necropsy revealed severe bacterial gastroenteritis with sepsis and toxemia, granulomatous myocarditis and cancer in her lungs. Histology comments suggest that the myocarditis could be related to undetected Chagas disease or some other unknown process. A gram stain was done and copious gram positive cocci in clusters and chains were observed. Strikingly, another pigtail, Z20164, who was less than a year old and in poor body condition—and who shared the enclosure with J06251—died ten days later.<sup>32</sup> She also "succumbed to a similar process with a severe meningitis with similar cocci bacteria and with growth from heart blood of 4+ Staphylococcus aureus and 2+ growth of viridans group Streptococcus sp. S. aureus is the suspect pathogen in both of these cases with less likely the pathogen being Streptococcus sp." However, there is no indication that a definitive etiologic agent was identified in either monkey.

The necropsy reports produced by WaNPRC do not provide enclosure identification information. Therefore, it is not possible to know if there are epizootiological patterns of disease in the WaNPRC colonies, despite WaNPRC's claim to OLAW that "...no trends related to cause of death have been identified." <sup>33</sup>

Arguably, infants are the **most vulnerable** monkeys in the WaNPRC colonies. Certainly, within the WaNPRC breeding colonies, infants are the **most valuable.** WaNPRC has two NIH grants—P510D010425 and U420D011123—that support the production of SPF pigtailed macaques who are then sold to experimenters. WaNPRC has stated that it costs approximately \$15,000 to produce a pigtailed macaque and they are sold for approximately \$13,000. Despite both the financial incentive and regulations, WaNPRC has consistently failed to ensure that the environment that their infants are born into is safe and healthy.

### B. Failure to fully investigate cause of death

Dozens of the 2018-2021 necropsy reports that PETA received and reviewed stated explicitly that histological evaluation of the monkey's tissues was not conducted—precluding WaNPRC's ability to properly diagnose underlying conditions, identify pathogens that could be interfering with experiments, and prevent any such pathogens from running rampant through the monkey populations at the facility. Below we have included just 10 examples, highlighting that multiple investigators, multiple studies and multiple excuses are listed in the necropsy reports. We trust that your investigation will document all instances in which histology is not conducted at the WaNPRC.

- On March 14, 2018, at WaNPRC's Seattle facility, a 13-year-old female pigtailed macaque
  —identified as T04352 and assigned to investigator Dorothy Patton's protocol, "Mn model
  development: Gonorrhea and Chlamydia infection and URT imaging by PET"—died.
  However, the cause of death was not determined. The necropsy report simply offered:
  "Histology was not requested due to lack of funding."<sup>34</sup>
- 2. On June 14, 2018, at WaNPRC's Seattle facility, a seven-year-old rhesus macaque—identified as A16236 and assigned to investigator Deb Fuller's protocol, "Optimization of a

<sup>32</sup> Ex. 29

<sup>31</sup> Ex. 28

<sup>&</sup>lt;sup>33</sup> Ex. 30

<sup>&</sup>lt;sup>34</sup> Ex. 31

- therapeutic HIV/SIV multi-antigen DNA vaccine"—died. The monkey had been inoculated with SIV Delta 8670 in November 2016. The necropsy report noted generalized lymphadenomegaly. Initially it was noted that histology was pending on representative tissues/organs preserved in formalin. However, on June 18, 2018, histology was canceled and the report was finalized.<sup>35</sup>
- 3. On August 23, 2018, at WaNPRC's Seattle facility, a rhesus macaque —identified as Z17122 and assigned to Shiu-Lok Hu's protocol, "Probiotic use as an adjuvant in HIV vaccine"—died. This animal had been challenged repeatedly intrarectally with SHIV.C.CH505.375H.dCT beginning in March 2018. The necropsy report stated that "there was no gross evidence of significant disease." Also: "Tissues/organs acquired as per research protocol. Histology not requested."<sup>36</sup>
- 4. On March 28, 2019, at WaNPRC's Seattle facility, a seven-year-old pigtailed macaque identified as A11230 and assigned to investigator Deb Fuller's protocol, "Evaluation of SIV co-infection on ZIKV pathogenesis in pig-tailed macaques"—died. The monkey had been inoculated with Zika virus on March 4, 2019. The necropsy report noted that histology was pending; this was later cancelled.<sup>37</sup>
- 5. On April 24, 2019, at WaNPRC's Seattle facility, a macaque—identified as Z15384 and assigned to Deb Fuller's protocol, "Prophylactic SHIV vaccine in NHP"—died. This animal had been inoculated intrarectally with SHIV in March 2019. The necropsy report indicated that "tissues/organs [were] acquired as per research protocol." However, the report also states: "Histology is declined."<sup>38</sup>
- 6. On April 30, 2019, at WaNPRC's Seattle facility, a five-year-old rhesus macaque identified as Z13327 and assigned to Deb Fuller's protocol, "Prophylactic SHIV vaccine in NHP"—died. The monkey had been inoculated intrarectally with SHIV in March 2019. However, the necropsy report stated: "Histology is declined."<sup>39</sup>
- 7. On October 30, 2019, at WaNPRC's Seattle facility, a 2.6-year-old long-tailed macaque identified as Z17071 and assigned to investigator Tom Burbacher's protocol, "Developmental neurotoxicity of domoic acid"—died. The necropsy report noted that the monkey's lungs were mildly erythematous and congested. However, histopathology was not requested.40
- 8. On May 7, 2020, at WaNPRC's Seattle facility, a five-year-old female rhesus macaque identified as A19122 and assigned to Deb Fuller's protocol, "Prophylactic SIV Vaccines and Optimization of different Adjuvant combinations in NHP"—died. The macaque had been vaccinated multiple times and then challenged intrarectally four times with SIV starting in January 2020. The animal's clinical history noted that she had developed moderate reduction in CD4+ lymphocytes. However, the necropsy report stated: "Histology is not requested."<sup>41</sup>
- 9. On June 15, 2020, at WaNPRC's Seattle facility, a rhesus macaque—identified as Z12209 and assigned to investigator Hans Peter Kiem's "Donor Pool" project—died. The animal's

<sup>36</sup> Ex. 33

<sup>&</sup>lt;sup>35</sup> Ex. 32

<sup>&</sup>lt;sup>37</sup> Ex. 34

<sup>&</sup>lt;sup>38</sup> Ex. 35

<sup>&</sup>lt;sup>39</sup> Ex. 36

<sup>&</sup>lt;sup>40</sup> Ex. 37

<sup>&</sup>lt;sup>41</sup> Ex. 38

- clinical history noted abnormal blood, and the necropsy report noted moderate, bilateral, caudal hydrocephalus. However, histology was not requested.<sup>42</sup>
- 10. On June 16, 2020, at WaNPRC's Seattle facility, a five-year-old rhesus macaque—identified as A19120 and assigned to investigator Deb Fuller's protocol, "Prophylactic SIV Vaccines and Optimization of different Adjuvant combinations in NHP"—died. The monkey had been vaccinated multiple times and then challenged intrarectally six times with SIV starting in February 2020. The necropsy report stated that the monkey had "multiple missing digits that are healed over." Histology was not performed. 43

# C. Failure to observe during surgeries or procedures that foreign objects were being left in monkeys

Many of the necropsy reports reviewed by PETA documented the discovery—during necropsy—of surgical sponges, syringe needles, and catheters that had been left in monkeys' bodies during procedures. WaNPRC's failure to identify these items while the monkeys were alive suggests that employees failed to conduct careful daily observations to ensure the health and well-being of monkeys. These failures would have contributed to the pain, discomfort, and distress experienced by the monkeys.

- 1. On December 12, 2019, at WaNPRC's Seattle facility, a three-year-old female rhesus macaque—identified as A19109 and assigned to investigator Hans Peter Kiem's "amfAR" protocol—died. Gross necropsy revealed that a tuberculin syringe needle was embedded in the tissue of the monkey's left thigh; and there was a 10 cm scar on the same hip. 44
- 2. On January 29, 2020, at WaNPRC's Seattle facility, a three-year-old male pigtailed macaque—identified as Z16047 and assigned to investigator Hans Peter Kiem's chemical marrow ablation and transplantation "UCLA CIRM" protocol—died. Gross necropsy was listed as "unremarkable." Histopathology revealed that a foreign object was present in the arterioles of a section taken from the lung and contributed to pulmonary arteriolar occlusion and inflammation. The pathologist noted that the finding was emphasized because "if large amounts of foreign material enter the pulmonary vasculature then there can be significant clinical consequences. The foreign material ... was in the vascular system and lodged in the small vessel described. Likely the material was either inadvertently injected or is a catheter fragment that embolized."<sup>45</sup>
- 3. On December 21, 2020, at WaNPRC's Seattle facility, a five-year-old female rhesus macaque—identified as A18128 and assigned to investigator Hans Peter Kiem's protocol, "Cell and gene therapy for HIV cure"—died. The monkey had been inoculated with SHIV in February 2019. Gross necropsy was unremarkable. Histopathology revealed that the inflammation on the monkey's spleen was likely associated with fragments of a surgical gauze sponge. 46
- 4. On February 1, 2021, at WaNPRC's Seattle facility, a seven-year-old female pigtail macaque—identified as Z13108 and assigned to investigator Dorothy Patton's protocol, "Optimizing a model of *Mycoplasma genitalium* reproductive tract infection in female

<sup>43</sup> Ex. 40

<sup>&</sup>lt;sup>42</sup> Ex. 39

<sup>&</sup>lt;sup>44</sup> Ex. 41

<sup>45</sup> Ex. 42

<sup>&</sup>lt;sup>46</sup> Ex. 43

Mn"—died. Gross necropsy revealed a mural mass in the urinary bladder and leiomyoma (fibroids) were suspected. Histopathology revealed that the bladder wall mass consisted of "necrotic debris, degenerate neutrophils and abundant monomorphic plant material (surgical gauze sponge." The pathologist concluded that the retained foreign object was likely a surgical sponge left during a C-section. 47

# D. Failure to perform daily observations of animals to assess health and well-being and/or failure to ensure that only monkeys who are compatible are caged together

Many of the necropsy reports reviewed by PETA documented the discovery—during necropsy—that monkeys were missing digits, ears, or other parts of their bodies. There is no indication that these injuries had been previously observed by husbandry staff or addressed by veterinary staff. WaNPRC's failure to identify these conditions while the monkeys were alive suggests that employees failed to conduct careful daily observations to ensure the health and well-being of monkeys. These failures would have contributed to the pain, discomfort, and distress experienced by the monkeys.

# D.1. Mutilated adult monkeys on experimental protocols

- 1. On June 7, 2018, at WaNPRC's Seattle facility, an eight-year-old male rhesus macaque—identified as A16144 and assigned to investigator Deb Fuller's protocol, "Immunogenicity and protective efficacy of therapeutic SIV vaccines in NHPs"—died. This monkey had been inoculated with SIV Delta 8670 in September 2016. Gross necropsy findings documented that this monkey was missing some fingertips and had moderate alopecia.<sup>48</sup>
- 2. On May 1, 2020, at WaNPRC's Seattle facility, a four-year-old rhesus macaque—identified as A19139 and assigned to investigator Deb Fuller's protocol, "Prophylactic SIV Vaccines and Optimization of different Adjuvant combinations in NHP"—died. This monkey had been vaccinated multiple times and was then challenged intrarectally three times with SIV in January 2020. Gross necropsy findings documented that this monkey's left ear was missing and healed over; and multiple digits on his hind leg were missing and healed over.<sup>49</sup>
- 3. On May 13, 2020, at WaNPRC's Seattle facility, a five-year-old female rhesus macaque—identified as A19118 and assigned to investigator Deb Fuller's protocol, "Prophylactic SIV Vaccines and Optimization of different Adjuvant combinations in NHP"—died. This monkey had been vaccinated multiple times and then challenged intrarectally twice with SIV in February 2020. Gross necropsy findings documented that this monkey had lost both ears and numerous digits.<sup>50</sup>
- 4. On May 14, 2020, at WaNPRC's Seattle facility, a five-year-old male rhesus macaque—identified as A19138 and assigned to investigator Deb Fuller's protocol, "Prophylactic SIV Vaccines and Optimization of different Adjuvant combinations in NHP"—died. This monkey had been vaccinated multiple times and then challenged intrarectally four times with SIV in February 2020. Gross necropsy findings documented that this monkey's left ear

<sup>48</sup> Ex. 45

<sup>&</sup>lt;sup>47</sup> Ex. 44

<sup>&</sup>lt;sup>49</sup> Ex. 46

<sup>&</sup>lt;sup>50</sup> Ex. 47

- was partially missing and healed over; and that multiple digits were missing and healed
- 5. On June 4, 2020, at WaNPRC's Seattle facility, a six-year-old male rhesus macaque identified as A19135 and assigned to investigator Deb Fuller's protocol, "Prophylactic SIV Vaccines and Optimization of different Adjuvant combinations in NHP"—died. This monkey had been vaccinated multiple times and then challenged intrarectally six times with SIV in February 2020. Gross necropsy findings documented that this monkey's left ear was mostly missing and healed over. Additionally, there were moderate, chronic, bilateral lung infarcts. Histology was not requested.<sup>52</sup>
- 6. On June 4, 2020, at WaNPRC's Seattle facility, a four-year-old female rhesus macaque identified as A19130 and assigned to investigator Deb Fuller's protocol, "Prophylactic SIV Vaccines and Optimization of different Adjuvant combinations in NHP"—died. This monkey had been vaccinated multiple times and then challenged intrarectally eight times with SIV in February 2020. Gross necropsy findings documented that this monkey's left ear was mostly missing and healed over; and that multiple digits were missing and healed over.53
- 7. On June 20, 2020, at WaNPRC's Seattle facility, a ten-year-old female rhesus macaque identified as A15108 and assigned to investigator Leslie Kean's protocol, "Kean SHIV Reservoir"—died. This monkey had been challenged with SHIV 1157ipd3N4 in November 2017. Gross necropsy findings documented that this monkey's ears were partially missing and healed over; and that the tips of three of her fingers were missing and healed over.<sup>54</sup>
- 8. On June 22, 2020, at WaNPRC's Seattle facility, an eleven-year-old female rhesus macaque—identified as A15106 and assigned to investigator Leslie Kean's protocol, "Kean SHIV Reservoir"—died. This monkey had been challenged with SHIV 1157ipd3N4 in November 2017. Gross necropsy findings documented that this monkey's ears were partially missing and healed over.<sup>55</sup>

# D.2. Mutilated infants in the breeding colony

Infants at WaNPRC are not only dying from inadequate veterinary care, they are also increasingly dying from traumatic injuries received in the breeding corrals and home cages. The Guide is explicit in its guidance:

Not all members of a social species are necessarily socially compatible. Social housing of incompatible animals can induce chronic stress, injury, and even death ... Risks of social incompatibility are greatly reduced if the animals to be grouped are raised together from a young age, if group composition remains stable, and if the design of the animals' enclosure and their environmental enrichment facilitate the avoidance of social conflicts. Social stability should be carefully monitored; in cases of severe or prolonged aggression, incompatible individuals need to be separated.

<sup>52</sup> Ex. 49

<sup>&</sup>lt;sup>51</sup> Ex. 48

<sup>&</sup>lt;sup>53</sup> Ex. 50

<sup>&</sup>lt;sup>54</sup> Ex. 51

<sup>&</sup>lt;sup>55</sup> Ex. 52

- 1. On February 21, 2018, at WaNPRC's SFP colony at NIRC, a four-week-old female pigtailed macaque identified as Z18047 was found "dead in cage." The necropsy findings included "severe, multicentric (head, chest, abdomen) trauma."56
- 2. On October 30, 2018, at WaNPRC's Mesa facility, a one-day-old male pigtailed macaque identified as Z18198 was found dead in group enclosure. The histological findings at necropsy indicated that "death was due to cagemate trauma." Also: "The pulmonary aspiration suggests dystocia which could have resulted in a relatively weak infant. There was no other evidence of disease in sections examined although autolysis impedes microscopic evaluation."57
- 3. On December 25, 2018, at WaNPRC's SFP colony at NIRC, a one-day-old male pigtailed macaque identified as Z18229 was found dead in the nursery. This macaque had been abandoned on Christmas Eve and was moved to the nursery. The necropsy findings determined that he suffered a "traumatic puncture wound of [his] thorax with peri-renal hemorrhage."58
- 4. On January 12, 2019, at WaNPRC's Mesa facility, a three-day-old male pigtailed macaque identified as Z19005 was found dead in the enclosure. The necropsy findings determined that his death was "due to severe, acute, cranial trauma from a cagemate." Notably, this monkey was the first birth in a new breeding group of animals—and the report stated, "The brain is visible through the hole and parts of it seem to be missing."59
- 5. On June 21, 2019, at WaNPRC's Seattle facility, a five-day-old male pigtailed macaque identified as Z19169 was repeatedly bitten in the head by his mother. The mother, who had recently been removed from an experimental protocol, had multiple medical issues requiring repeated sedations shortly after the infant's birth. The infant was euthanized. The necropsy revealed "severe, subcutaneous hemorrhage of the cranium ..., numerous complete skull fractures ... and cerebral cortical tissue protruding through various holes in the skull."60
- 6. On October 6, 2019, at WaNPRC's SFP colony at NIRC, a newborn male pigtailed macaque identified as Z19256 was "found dead with a crushed skull." The necropsy findings were "consistent with cagemate trauma."61
- 7. On January 27, 2020, at WaNPRC's Seattle facility, a 1.5-month-old female pigtailed macaque identified as Z19278 was "euthanized due to trauma." She had been assigned to the "breeding colony." The necropsy report documented an open "head wound, with penetration of skull bone fragments into the brain" as well as "frontal lobe and mild retrobulbar hemorrhage and brain injury."62
- 8. On October 14, 2020, at WaNPRC's Mesa facility, a two-week-old male pigtailed macaque identified as Z20176 was found dead with his mother holding him. The necropsy report describes blunt trauma to the head as the likely cause of death, and post-mortem trauma includes wounds to the head, neck, and throat.<sup>63</sup>
- 9. On April 17, 2021, a WaNPRC's Mesa facility, a one-day-old newborn pigtailed macaque identified as Z21064 was found dead in the 212 enclosure. The necropsy report described

<sup>57</sup> Ex. 54

<sup>&</sup>lt;sup>56</sup> Ex. 53

<sup>&</sup>lt;sup>58</sup> Ex. 55

<sup>&</sup>lt;sup>59</sup> Ex. 56

<sup>&</sup>lt;sup>60</sup> Ex. 57

<sup>&</sup>lt;sup>61</sup> Ex. 58

<sup>&</sup>lt;sup>62</sup> Ex. 59

<sup>63</sup> Ex. 60

- multiple skull fractures and broken ribs, and the suspected cause of death was traumatic brain injury.<sup>64</sup>
- 10. On May 7, 2021, at WaNPRC's Mesa facility, a 20-day-old female pigtailed macaque identified as Z21065 was bitten by an adult male in a breeding enclosure. The necropsy report describes "acute, severe, skull fractures with hemorrhage and brain avulsion." 65
- 11. On June 29, 2021, at WaNPRC's Mesa facility, a newborn male pigtailed macaque identified as Z21111 was found dead in the cage, with bite wounds to his genitals, limbs, and tail. The necropsy report concluded: "Gross and histologic findings indicate cage mate induced trauma as cause of death." 66
- 12. On November 29, 2021, at WaNPRC's Mesa facility, a newborn female pigtailed macaque identified as Z21209, caged only with her mother, died from bite wounds to her head and face. The necropsy report also noted that the infant's eyes were missing.<sup>67</sup>

WaNPRC has consistently failed to ensure the stable social composition within the pigtailed macaque breeding enclosures and the consequences for the infants have been horrific.<sup>68</sup> In the wild, pigtailed macaques live in large multi-male, multi-female groups with strong female bonds and stable matrilines. The consequences of the failure to replicate this social structure in captive breeding colonies is undeniable. Unrelated females crammed into a fraction of the normal home range, a single adult male confined with them, the inability of females to choose who they mate with, the lack of a social system with the necessary checks and balances and the sheer deprivation of life in a 10 x 6 foot cage invariably results in aggression, injury and death.

### Conclusion

For more than 30 years, NIH has funneled hundreds of millions of taxpayer dollars to develop and maintain healthy monkey colonies around the U.S. PETA has uncovered thousands of pages of documents revealing that the University of Washington's pigtailed colonies are ravaged by diarrheal diseases, fungal infections, and parasites that are spread by assassin beetles and mosquitoes. Not only do these unintended infections make the monkeys very ill, it actually subverts WaNPRC's claims that these monkeys are appropriate and well characterized biomedical models for human diseases. The UW primate center has been selling these monkeys to experimenters around the country.

WaNPRC veterinarians, pathologists and investigators have failed to consistently identify the etiological agents that are killing monkeys in the breeding colony as well as those monkeys assigned to experimental protocols. Infants and adult monkeys are mauled and mutilated. Foreign objects have been left in monkeys.

None of the 59 incidents included in this complaint have been self-reported to OLAW. None of these incidents has been reported during the monthly IACUC meetings at which UW's Attending Veterinarian and WaNPRC's Mesa facility veterinarians are required to describe adverse events. WaNPRC pathologist Robert Murnane and WaNPRC veterinarian Charlotte Hotchkiss served as

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<sup>&</sup>lt;sup>64</sup> Ex. 61

<sup>65</sup> Ex. 62

<sup>&</sup>lt;sup>66</sup> Ex. 63

<sup>&</sup>lt;sup>67</sup> Ex. 64

<sup>&</sup>lt;sup>68</sup> Ex. 65

IACUC members for the majority of the period covered by the records that we reviewed for this complaint. Hotchkiss is also the PI of the WaNPRC U42 SPF breeding colony grant. The former interim director of WaNPRC, Sally Thompson-Iritani, who herself is a veterinarian and served as the Director of UW's Office of Animal Welfare prior to moving to leadership positions at WaNPRC and is co-PI on the WaNPRC U42 grant never revealed these adverse events to the IACUC. Thompson-Iritani now serves as UW's Institutional Official.

We respectfully request a full investigation into the concerns that we have summarized here and any underlying issues that may be exposed. If noncompliance is found, we urge you to take swift and decisive action against the institution.

I look forward to hearing from you regarding this matter and am available to assist you in your investigation. I can be contacted at <u>LisaJE@peta.org</u>. Thank you.

Sincerely,

Lisa Jones-Engel, PhD

Senior Science Advisor, Primate Experimentation

Laboratory Investigations Department

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