



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare
6700B Rockledge Drive, Suite 2500, MSC 6910
Bethesda, Maryland 20892-6910
Home Page: <http://grants.nih.gov/grants/olaw/olaw.htm>

FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare
6700B Rockledge Drive, Suite 2500
Bethesda, Maryland 20817
Telephone: (301) 496-7163
Facsimile: (301) 480-3387

DATE: November 9, 2022

TO: Lisa Jones-Engel, Ph.D.
Senior Science Advisor, Primate Experimentation

FROM: Senior Animal Welfare Program Specialist, Office of Laboratory Animal Welfare

SUBJECT: Animal Welfare Investigation - Animal Welfare Assurance A3464-01 [Case 11Z]

The Office of Laboratory Animal Welfare (OLAW) has completed its investigation regarding allegations by People for the Ethical Treatment of Animals (PETA) concerning the treatment of monkeys held in colonies by the University of Washington and the affiliated Washington National Primate Research Center (WaNPRC). Our investigation included a review of pathology and necropsy reports. The investigation did not confirm any additional allegations contained in your May 10, 2022 document.

The final report received included additional information requested by OLAW. It is acknowledged that all nonhuman primates in colonies at WaNPRC are supported by PHS grants. It is understood that a necropsy is generally performed with all unexpected deaths at the WaNPRC. Regarding the 25 pathology reports submitted to OLAW describing infant macaques, 8 reports involved animals located at another institution. Therefore, those cases were not considered in this report. The remaining reports involved infants that were found deceased or died during treatment and two infants that were euthanized by a veterinarian. Each case was evaluated as it occurred, and follow-up assessments of the dam/breeding group of origin were made as necessary. It is noted that these incidents occurred in different enclosures, involving different dams, and did not meet the internal criteria for more generalized investigation.

Several pathology reports described infants that were found dead or required euthanasia. These incidents occurred in different group enclosures. The possibility of a common cause was considered, and no commonalities were identified upon review. The reports with necropsy findings suggestive of infectious processes resulted in the dams associated with those infants being closely monitored. Those dams did not exhibit any significant clinical signs during the time of the infant deaths. It is also stated there was no change in overall colony health over this period that indicated a more widespread issue.

It is stated that regardless of age, all animals at WaNPRC are assessed twice daily at a minimum by trained technicians. The veterinary staff is promptly notified of abnormalities, they assess the animal, and a clinical case is opened when appropriate. The dams are monitored for appropriate handling and lack of aggression toward the infant. Minimal disruptions to the pair may occur to facilitate dam and infant bonding if the infant appears healthy. It is understood an in-depth health assessment of both the dam and infant occurs after parturition in a timely manner.

One allegation referenced a diagnostic laboratory necropsy report, which described an infant macaque found dead and the dam as lethargic with diarrhea. A fecal sample was collected from the dam, but not included in the report. Another necropsy report stated a female macaque collapsed in her enclosure and was euthanized after her condition did not improve with emergency treatment. Findings from the IACUC determined these two animals presented differently at the onset of disease (respiratory disease in one case and the second case presented as neurologic progressing to gastrointestinal signs). The shared location and unexpected mortalities prompted additional microbiological sampling by the clinical veterinarian due

to increased concern. It is understood the cage of origin was closely monitored, no other animals were significantly ill during, or immediately following, these mortalities. As stated in documents provided by PETA, it was concluded that the suspected pathogen was possibly *Staphylococcus aureus*, which is a known opportunistic pathogen in macaque species. Based on this information and in addition to no other animals in the same enclosure becoming ill, no additional actions were designated to determine contributing factors regarding the two animal deaths.

An additional allegation stated dozens of necropsy reports noted that histological evaluation was not performed, and these reports indicate a failure to fully investigate cause of death. Findings from the IACUC state these animals were euthanized at pre-determined study endpoint dates. It is understood that all nonhuman primates minimally undergo a gross necropsy. Regarding research animals exhibiting no clinical signs of disease, the necropsy procedures are driven by the study protocol. However, it is noted the clinical veterinarian, or the pathologist can request tissue analysis beyond what is described in the protocol as needed. Any changes to the preventative health program are implemented as needed based on colony health statistics which are reviewed on an ongoing basis.

An additional allegation stated there was a failure to observe surgeries/procedures which resulted in the discovery of foreign bodies in macaques, and four cases were highlighted. The IACUC findings determined the animals described in these reports were euthanized due to experimental endpoints, and none of these animals exhibited clinical signs related to the findings. Furthermore, these four cases were reviewed by the USDA and no citations were issued. It is stated that medical and surgical procedures are always performed by trained staff members. Also, any surgery involving an open body cavity utilizes a sponge count, and animals are monitored multiple times per day. If clinical signs suggest a potential foreign body is present, then diagnostics and treatment are provided, which may include an exploratory surgery.

An additional allegation stated that there has been a failure to perform daily observation of animals to assess health and well-being and/or failure to ensure that only compatible monkeys are housed together. Several necropsy reports were highlighted and described missing fingertips, ears, etc. The IACUC findings noted that daily observations are performed by husbandry and veterinary technicians. Based on the observation, it may be documented on a cage side daily observation sheet, or the veterinarian may be contacted directly. If the observation warrants, a medical case will be opened, and subsequent interventions are documented until the case is resolved. Chronic conditions that do not require any intervention are not recorded as a daily observation once healed. Animals received from another facility with healed amputations may have them noted during an intake physical exam but are not typically recorded during daily observations. Conversely, chronic conditions that require ongoing treatment may either be entered as a clinical case with an indefinite end date or entered as an alert. It is stated that the research staff are notified of all diagnoses and interventions as they occur.

The findings from the IACUC determined trained animal behaviorists regularly monitor and work with animals. Assessment of animals occurs on an ongoing basis, and unusual behaviors noted by staff are reported promptly to the behavioral staff. The Behavioral Management Staff (BMS) is involved in all social formation, and there are no exceptions. An extensive database is used to track social history and pertinent information. Additionally, newly formed social pairs or groups are closely observed until they are considered stable.

An additional allegation stated infants at WaNPRC are increasingly dying from traumatic injuries received in breeding corrals and home cages. These reports include descriptions of infant deaths due to trauma from cage mates, dams, etc. It is understood that breeding females are initially selected primarily for overall health to ensure pregnancy and lactation will not be detrimental to their physical health.

Behavioral history is maintained on all primates and utilized in the evaluation of potential female breeders. Following parturition, the infant/dam pair is regularly visually assessed. Newborn infants are observed cage side for appropriate orientation and nursing on the dam, and aggression toward the infant. It is understood the BMS monitors formations and new introduction, and each new group is monitored twice per day or more if necessary. Also, dominance hierarchies are established and recorded with follow-up rank checks to assess if the hierarchy is stable. Once a formation is established, every group is observed by BMS one to two times per month.

The above explanations are consistent with OLAW's expectations regarding provision of adequate veterinary care and that the facility is operating in full compliance with the provisions of the PHS Policy on Humane Care and Use of Laboratory Animals. OLAW shares your concern for the welfare of laboratory animals. We find no cause for further action by this office at this time.

Sincerely,

Jacquelyn T.
Tubbs -S

Digitally signed by Jacquelyn T.
Tubbs -S
Date: 2022.11.09 08:44:22
-05'00'

Jacquelyn Tubbs, DVM, DACLAM
Senior Animal Welfare Program Specialist
Division of Compliance Oversight
Office of Laboratory Animal Welfare



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October 28, 2022

Re: Animal Welfare Assurance
A3464-01 [OLAW Case 11Z]

Sally Thompson-Iritani, DVM, PhD, CPIA, CCFP
Associate Vice Provost
University of Washington
4000 15th Ave NE- Box 357330
Seattle, WA 98195

Dear Dr. Thompson-Iritani,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your September 16, 2022 letter in response to allegations of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of Washington (UW) and the affiliated Washington National Primate Research Center (WaNPRC). These allegations were received from People for the Ethical Treatment of Animals (PETA) regarding necropsy and pathology reports submitted to OLAW for review.

The final report received details the investigative results from the IACUC regarding the additional information requested by OLAW. It is acknowledged that all nonhuman primates in colonies at WaNPRC are supported by PHS grants. Per the report, a necropsy is generally performed with all unexpected deaths at the WaNPRC. Regarding the 25 pathology reports describing infant macaques, 19 of those cases met the date of criteria specified in the letter from OLAW. It is stated 8 of the 19 cases involved animals located at New Iberia Research Center. Therefore, those cases were not considered in this report. The 11 remaining cases involved nine infants that were found deceased or died during treatment and two infants that were euthanized by a veterinarian. Each case was evaluated as it occurred, and follow-up assessments of the dam/breeding group of origin were made as necessary. It is noted that these 11 cases occurred over a 3-year period, in 10 different enclosures, 11 different dams, and did not meet the internal criteria for more generalized investigation. Regarding the five highlighted infant cases, these incidents occurred in four different group enclosures over a 2-month period, and the prospect of a common cause was considered. It is understood upon review, no commonalities were identified. The cases with necropsy findings suggestive of infectious processes resulted in the dams associated with those infants being closely monitored. Those dams did not exhibit any significant clinical signs during the time of the infant deaths. It is also stated there was no change in overall colony health over this period that indicated a more widespread issue.

The report states that regardless of age, all animals at WaNPRC are assessed twice daily at a minimum by trained technicians. The veterinary staff is promptly notified of abnormalities, they assess the animal, and a clinical case is opened when appropriate. It is understood that animals may be monitored more frequently as appropriate, for conditions such as females in late gestation and newly formed social groups. On the day of birth, new infants are assigned an ID number/added to the census. Also, newborn infants are observed cage side for proper orientation and nursing on the dam. The dams are monitored for appropriate handling and lack of aggression toward the infant. Minimal disruptions to the pair may occur to facilitate dam and infant bonding if the infant appears healthy. It is understood the dam is sedated ~3-10d after parturition for an in-depth health assessment of both the dam and infant.

One allegation referenced a diagnostic laboratory necropsy report dated May 5, 2019, which described an infant macaque found dead and the dam as lethargic with diarrhea. A fecal sample was collected from the dam, but not included in the report. Another necropsy report dated June 20, 2021, stated a female macaque collapsed in her enclosure and was euthanized after her condition did not improve with emergency treatment. Findings from the IACUC determined these two animals presented differently at the onset of disease (respiratory disease in one case and the second case presented as neurologic progressing to gastrointestinal signs). The shared location and unexpected mortalities prompted additional microbiological sampling by the clinical veterinarian due to increased concern. The report notes the cage of origin was closely monitored, no other animals were significantly ill during, or immediately following, these mortalities. As stated in documents provided by PETA, it was concluded that the suspected pathogen was possibly *Staphylococcus aureus*, which is a known opportunistic pathogen in macaque species. Based on this information/conclusion in addition to no other animals in the same enclosure becoming ill, no additional actions were designated to determine contributing factors regarding the two animal deaths.

An additional allegation stated dozens of necropsy reports noted that histological evaluation was not performed, and these reports indicate a failure to fully investigate cause of death. Findings from the IACUC state these animals were euthanized at pre-determined study endpoint dates. It is understood that all nonhuman primates minimally undergo a gross necropsy. Regarding research animals exhibiting no clinical signs of disease, the necropsy procedures are driven by the study protocol. It is also understood that the clinical veterinarian or the pathologist can request tissue analysis beyond what is described in the protocol as needed. Per the report, the colony health statistics are reviewed on an ongoing basis and shared at least quarterly with the Attending Veterinarian. Any changes to the preventative health program are implemented as needed based on this information.

An additional allegation stated there was a failure to observe surgeries/procedures which resulted in the discovery of foreign bodies in macaques, and four cases were highlighted regarding this allegation. The IACUC findings determined the animals described in these cases were euthanized due to experimental endpoints, and none of these animals exhibited clinical signs related to the findings. Furthermore, these four cases were reviewed by the USDA and no citations were issued. It is stated that medical and surgical procedures are always performed by trained staff members. Also, any surgery involving an open body cavity utilizes a sponge count, and animals are monitored multiple times per day. If clinical signs suggest a potential foreign body is present, then diagnostics and treatment are provided, which may include an exploratory surgery.

An additional allegation stated that there has been a failure to perform daily observation of animals to assess health and well-being and/or failure to ensure that only compatible monkeys are housed together. Eight reports were highlighted and described missing fingertips, ears, etc. in the necropsy reports. The IACUC findings noted that daily observations are performed by husbandry and veterinary technicians. Based on the observation, it may be documented on a cage side daily observation sheet, or the veterinarian may be contacted directly. If the observation warrants, a medical case will be opened, and subsequent interventions are documented until the case is resolved. Chronic conditions that do not require any intervention are not recorded as a daily observation once healed. Animals received from another facility with healed amputations may have them noted during an intake physical exam but are not typically recorded during daily observations. Conversely, chronic conditions that require ongoing treatment may either be entered as a clinical case with an indefinite end date for conditions such as diabetes and arthritis. It is noted that the veterinary staff informs research staff of all diagnoses and interventions as they occur. It is understood that signage will be added (at the room or cage level) for chronic conditions that could be impacted by routine husbandry procedures or handling.

The findings from the IACUC determined trained animal behaviorists regularly monitor and work with animals at the Seattle and Arizona sites. Assessment of animals occurs on an ongoing basis, and unusual behaviors noted by staff are reported promptly to the behavioral staff. The Behavioral Management Staff (BMS) is involved in all social formation, and there are no exceptions. An extensive database is used to

track social history and pertinent information. Also, newly formed social pairs or groups are closely observed until they are considered stable.

An additional allegation stated infants at WaNPRC are increasingly dying from traumatic injuries received in breeding corrals and home cages. Multiple necropsy reports are cited as examples regarding this allegation. These reports include descriptions of infant deaths due to trauma from cage mates, dams, etc. It is understood that breeding females are initially selected primarily for overall health to ensure pregnancy and lactation will not be detrimental to their physical health. Behavioral history is maintained on all primates and utilized in the evaluation of potential female breeders. Following parturition, the infant/dam pair is regularly visually assessed. Again, newborn infants are observed cage side for appropriate orientation and nursing on the dam, and aggression toward the infant. It is understood the BMS monitors formations and new introduction for the first week using quantitative record keeping. Each new group is monitored twice per day or more if necessary. Also, dominance hierarchies are established and recorded with monthly follow-up rank checks to assess if the hierarchy is stable. Once a formation is established, every group is observed by BMS one to two times per month using the same quantitative data collection methods.

Based on its assessment of this explanation, OLAW understands that the University of Washington (not Arizona) WaNPRC is compliant with the provisions of the PHS Policy on Humane Care and Use of Laboratory Animals and continues to report incidents to this Office as appropriate. We will provide this assessment to PETA as well.

We appreciate being informed of these matters and find no cause for further action by this Office.

Sincerely,

Jacquelyn T. Tubbs -S
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Jacquelyn T. Tubbs -S
Date: 2022.10.28
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Jacquelyn Tubbs, DVM, DACLAM
Senior Animal Welfare Program Specialist
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC Contact

Robert M. Gibbens, DVM, Director, Animal Welfare Operations

Sept. 16, 2022

Dr. Jacquelyn Tubbs

Senior Animal Welfare Program Specialist
Division of Compliance Oversight
Office of Laboratory Animal Welfare, NIH
6700B Rockledge Drive, Suite 2500, MSC 6910
Bethesda, MD 20892
olawdco@od.nih.gov

Re: Animal Welfare Assurance A3464-11Z

Dear Dr. Tubbs,

Please find attached a complete response to your letter dated July 15, 2022. As instructed an investigation avoiding Conflict of Interest was completed by our IACUC and their analysis and requested documents are included.

If you have any questions or require further information, please let us know.

Sincerely,

(b) (6)

Sally Thompson-Tritani (she/her), DVM/PhD, CPIA, CCFP
Institutional Official, University of Washington Animal Care and Use Program
Asst. Vice Provost, Animal Care, Outreach & 3Rs
Clinical Associate Professor, DEOHS, SPH
(b) (6)/sti2@uw.edu

Cc Dr. Jane Sullivan, UW IACUC Chair
Dr. Christina Cruzen, UW Attending Veterinarian

(b) (6)

W Office of Animal Welfare

September 16, 2022

Re: Animal Welfare Assurance A3464-01 (OLAW Case 11Z)

Dear Dr. Thompson-Iritani,

The IACUC appreciates the opportunity to verify for OLAW that our program meets the expectations for exceptional animal care and use and remains compliant with Animal Welfare Act regulations and our Assurance with OLAW. The allegations made by PETA have also been investigated by the USDA on 4 separate visits with no citations issued, and a team from OLAW recently visited our nonhuman primate facility in Arizona and found the program commendable and compliant with all regulations and expectations.

Below are the results of my investigation into the circumstances surrounding the allegations described in Dr. Tubbs' letter dated July 15, 2022.

Allegation #1a: Regarding these findings, please state whether a root cause analysis was conducted to determine if the above incidents were related. Please describe the program for monitoring animals, particularly infants in primate colonies and whether additional postmortem evaluations and other diagnostic procedures are performed to determine trends in colony health.

Necropsy is typically performed with all unexpected deaths at the Washington National Primate Research Center (WaNPRC), and each case is evaluated in terms of potential risk to the dam and/or other members of the colony based on clinical signs and necropsy findings. Of the 25 necropsy reports noted in the submitted complaint, 19 of the cases meet the date criteria specified for our response. Of these 19 cases, 8 of them were for animals that were born and died at New Iberia Research Center and are thus not considered in our response (see UW-NIRC Interinstitutional Agreement). For the remaining 11 total cases, 9 infants were found dead or died during treatment and 2 infants were euthanized by the veterinarian. As per our standard practice, each case was evaluated as it occurred, and follow-up assessments of the dam or breeding group of origin were made as needed. These 11 cases occurred over a 3-year period, from 10 different enclosures, to 11 different dams, and did not meet our internal criteria for more generalized investigation. Due to the temporal proximity of the five highlighted infant cases, we did consider the possibility of a common cause. However, upon review, no commonalities were noted. These 5 cases occurred over a 2-month period in 4 different group enclosures. In the cases with necropsy findings suggestive of infectious processes, the dams for those infants were closely monitored and did not develop any significant clinical signs around the time of the infant deaths. Additionally, there was no change in overall colony health over this period that suggested a more widespread issue.

Regardless of age, all animals at WaNPRC are assessed a minimum of twice daily by trained technicians. Abnormalities are promptly reported to veterinary staff, and the veterinary staff assesses the animal and opens a clinical case when appropriate. Animals under medical care, females in late gestation, newly formed social groups, or other special cases may be monitored at an increased frequency as appropriate. New infants are reported to veterinary staff and assigned an ID number/added to the census on the day of birth. Newborn infants are observed cageside for correct orientation and nursing on the dam, and dams are monitored for appropriate

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handling and lack of aggression toward the infant. If the infant appears healthy, minimal disruptions to the pair or group may occur, to facilitate dam and infant bonding. The infant will be assessed, along with the full group, multiple times per day as described above. Dams will be sedated approximately 3-10 days after giving birth to facilitate a more in-depth health assessment of both the dam and the infant. This may be done earlier or later at the discretion of the veterinarian.

Allegation #1b: Regarding these findings, please state whether a root cause analysis was conducted to determine if the above incidents were related.

These two animals presented very differently at the onset of disease – one as a respiratory case and the other as a neurological and then gastrointestinal case. Despite the difference in disease presentation, the shared location and two unexpected mortalities did cause elevated concern by the clinical veterinarian as indicated by the additional microbiological sampling performed at the necropsy of the second animal as well as the comments in that necropsy record of a possible similar causative organism. The cage or origin was closely monitored, and no other animals were significantly ill during, or immediately following, these animal deaths. Our conclusion, as quoted in the complaint submitted by PETA, was that “*S. aureus* was the suspected pathogen in both cases.” Given that *Staphylococcus aureus* is generally regarded as a commensal/opportunistic pathogen in macaque species combined with the fact that no other animals in the enclosure were ill, no further action was indicated to evaluate additional contributing factors to the demise of the two animals.

Allegation #2: Please clarify if these animals were euthanized per protocol (i.e., study endpoint) or due to animal health/welfare concerns. Please provide the justification for not performing histology regarding these reports. Please provide a summary of the steps taken upon finding a deceased nonhuman primate including all post-mortem evaluations, colony health statistics, changes in preventive medicine, and other relevant preventive steps taken.

All seven cases were animals assigned to study protocols that were euthanized at pre-determined study endpoint dates. All nonhuman primates minimally undergo a gross necropsy. For research animals without clinical signs of disease, the specific necropsy procedures are driven by the study protocol the animal is assigned to. In all cases, the clinical veterinarian or the pathologist can request tissue analysis beyond what is specified in the research protocol as needed. These decisions are made on a case-by-case basis using veterinary discretion. Colony health statistics are reviewed on an ongoing basis by the Associate Director and shared at least quarterly with the Attending Veterinarian. Changes in the preventative health program would be implemented as needed based on this information.

Allegation #3: Please clarify whether the animals associated with these reports were euthanized based on study endpoints or due to animal welfare concerns, especially those linked to the discovery of foreign bodies. Please describe the procedures/processes in place to mitigate the likelihood of foreign bodies occurring in animal models.

All 4 cases were for animals that were euthanized due to experimental endpoints. None of the animals had clinical signs related to the findings. All 4 of these cases were recently reviewed by the USDA and no citations were issued. To mitigate risk of foreign bodies after surgery, implanted devices and medical equipment are high quality, medical grade products. Medical and surgical procedures are always performed by trained staff members. Any

surgery involving an open body cavity (e.g. thoracotomy or laparotomy) utilizes a sponge count. Animals are monitored multiple times per day, and if clinical signs indicate a potential foreign body the animal will undergo diagnostics and treatment as appropriate, including physical examination, radiography, endoscopy and/or exploratory surgery.

Allegation #4: Please describe how daily health observations of animals are documented? Please describe how chronic conditions such as missing fingers, fingertips, etc. are documented and recorded in medical records. How are research, husbandry, and veterinary staff notified when an animal has been identified with a chronic condition? Are trained behaviorists actively involved in evaluating compatibility prior to establishing social groups? Are records being kept regarding primate interactions, aggression, affiliative behavior, and composition of the groups?

Daily observations are made by a combination of husbandry technicians and veterinary technicians. Dependent on the nature of the observation, it may be documented on a cageside daily observation sheet or the veterinarian may be contacted directly. If the observation warrants, the veterinarian will open a medical case in the electronic record system, and document subsequent observations/intervention until that case is resolved. Chronic conditions that do not require any intervention, such as missing digits, will not be recorded as a daily observation once healed. Typically, these are noted only when the inciting injury occurs and may be noted in routine physical exam findings. Animals that are received from other facilities with fully healed amputations may have them noted during an intake physical examination but are not usually recorded during daily observations. Other chronic conditions, may either be entered as a clinical case with an indefinite end date (for conditions that require ongoing treatment or monitoring, such as hepatomegaly, diabetes, or arthritis) or may be entered simply as an alert (for conditions that only require notification but no treatment or monitoring, such as ketamine reactivity or limited mobility). Veterinary staff notifies research staff of all diagnoses and interventions as they occur. Veterinary staff, research staff, and husbandry staff have access to view the medical records of animals at all times. Signage at the room or cage level will be added for chronic conditions that could be impacted by routine husbandry procedures or handling.

Trained animal behaviorists routinely monitor and work with animals at both the Seattle and Arizona sites. Animals are assessed on an ongoing basis. If any staff note unusual behaviors, they will report those observations promptly to the behavioral staff. The Behavior Management Staff is involved in all social formations without exception. The behavioral staff has an extensive database to track social history and pertinent behavioral information. Newly formed social pairs or groups are very closely observed until all staff are confident in their stability. On a recent visit to the Arizona site, the OLAW visitors commented specifically that they "appreciated the behavior management services supervisor's detailed review of the environmental enrichment program; the description of how behavioral assessments are conducted, and interventions established to address potential stereotypies."

Allegation #5: Please describe the process for determination of female macaques identified as qualified for becoming potential breeders, processes in place to monitor and establish successful social structures (i.e., compatible breeding pairs, compatible social groups, etc.) among primate colonies.

Breeding females are initially selected primarily for overall health to ensure pregnancy and lactation will not be detrimental to their physical health. Behavior history is maintained on all animals and is also used to evaluate

potential female breeders. Following delivery, the infant/dam pair is visually assessed regularly. As described above, newborn infants are observed cageside for correct orientation and nursing on the dam, and dams are monitored for appropriate handling and lack of aggression toward the infant. The Behavior Management Staff (BMS) observes formations and new introductions for the first week at minimum using quantitative record keeping. Each new group is observed twice per day or more as needed. Dominance hierarchies are also established and recorded with follow-up monthly rank checks conducted by BMS to assess if hierarchy is stable. Once formation is established, every group is observed by BMS 1-2x per month using the same quantitative data collection methods.

Please have the IACUC consider if any of these occurrences represent programmatic failures. Please also include information regarding any PHS/NSF/DHHS funding of activities related to the occurrences, including grant or contract numbers. If other reportable non-compliances have occurred during this period, please also include them with the report.

We do not consider any of these occurrences to be representative of programmatic failures. All nonhuman primates in colonies at WaNPRC are supported by PHS grants P51OD010425 (Seattle) and U42OD011123 (Arizona). Some of the specific animals covered in this request may also have been assigned to research studies with separate grant numbers at some point in life. All non-compliances are reported to both the IACUC and OLAW as they occur.

Please let me know if you need additional information.

Sincerely,

(b) (6)

Jane M Sullivan, Ph.D.
Associate Professor,
Dept. of Physiology & Biophysics
Chair, UW IACUC

**INTERINSTITUTIONAL AGREEMENT ON REVIEW OF
LABORATORY ANIMAL USE AND FACILITIES**

The University of Washington ("UW") and University of Louisiana at Lafayette, New Iberia Research Center ("NIRC") share a mutual concern for the appropriate and humane care and use of laboratory animals in research, teaching, and testing activities conducted at their respective institutions. UW and NIRC may be referred to individually as an "Institution" or collectively as the "Institutions". Each Institution has policies and procedures that are in compliance with the Animal Welfare Act and the Public Health Service Policy for the humane care and use of laboratory animals. Each has on file with the Office of Laboratory Animal Welfare ("OLAW") an Animal Welfare Assurance statement and OLAW has assigned compliance certification number D16-00292 to the UW and D16-00016 to NIRC. Each institution is accredited by the Association for Assessment and Accreditation of Laboratory Animal Care International ("AAALAC").

The above-named institutions enter into this Agreement in order to establish mutually beneficial animal use and facility review procedures. Provisions are as follows:

- A. This Agreement is applicable to all research, teaching, and testing involving live vertebrate animals by personnel holding joint appointments in the two Institutions or by collaboration between personnel in the two Institutions; and in which animals are housed or used at one Institution as part of a project funded by the other Institution.
- B. Review of animal use activities will be conducted by the Institutional Animal Care and Use Committee ("IACUC") of the Institution where the animals are primarily housed and the research is primarily performed, using the forms of that Institution. Each Institution may request and be provided a copy of approved protocols, including revisions and amendments, involving their animals at the other Institution.
- C. No component of work being done at either Institution may be further subcontracted or performed at another location without first obtaining approval from the funding Institution. Additional documentation will need to be collected and reviewed prior to the IACUC approval of work at another Institution.
- D. Each Institution will submit to the other Institution a copy of its semiannual facility inspection and program review, or relevant portions of the document, including any deficiencies and corrections, so that each IACUC is not required to inspect the animal use areas of the other Institution.
- E. The Attending Veterinarian ("AV") at each Institution will assure the provision of adequate veterinary care in compliance with the Animal Welfare Act (9 CFR, Chapter 1, Part 2, Subpart C, Section 2.33) and the Health Research Extension Act of 1985 and its implementing regulations as put forth by OLAW, for all animals housed and used at their Institution.
- F. Each Institution will be responsible for all reporting requirements involving the animals housed, or primarily housed, at their facility and for whom use was approved by their IACUC.
- G. Transportation of animals between Institutions will be in accordance with the policies of the receiving Institution.
- H. Each Institution will maintain accreditation by AAALAC, an updated assurance statement with OLAW, and, if applicable, United States Department of Agriculture ("USDA") registration. Each Institution is responsible for promptly notifying the other institution of any of the following events: (i) any changes or loss of its AAALAC accreditation status; (ii) material changes to its assurance or USDA registration; and (iii) adverse events regarding shared animal use activities that were reported to USDA, OLAW, AAALAC, or any other oversight organization or agency. Each Institution agrees to provide the other Institution, upon request, with a copy of any report described in this subsection.
- I. This Agreement shall begin on the Effective Date and continue for five years ("Initial Term") unless terminated by either party with reasonable written notification. After completion of the Initial Term this Agreement may be extended by mutual agreement in writing signed by the Institutions.

"Effective Date": 11/17/17

The University of Washington

(b) (6)

University of Louisiana at Lafayette,
New Iberia Research Center

(b) (6)

Thea Brabb, DVM, PhD, DACLAM Date
Attending Veterinarian

(b) (6)

McCoy, Devora (NIH/OD) [E]

From: Sally Thompson-Iritani <sti2@uw.edu>
Sent: Friday, September 16, 2022 7:17 PM
To: OLAW Division of Compliance Oversight (NIH/OD)
Cc: Jane Sullivan; Christina L Cruzen; Office of Animal Welfare
Subject: [EXTERNAL] RE: OLAW Case A3464-11Z
Attachments: Response_UW_OLAW_A3464-11Z_final.pdf

Follow Up Flag: Follow up
Flag Status: Flagged

Hello Devora –

Please find our final response to OLAW Case A3464-11Z. If you have any questions or require clarification then please don't hesitate to reach out any time.

Thank you -

Sally Thompson-Iritani, DVM/PhD, CPIA, CCFP
Asst. Vice Provost, Animal Care, Outreach & 3Rs
Clinical Associate Professor, DEOHS, SPH
University of Washington, Seattle, WA
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From: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Sent: Thursday, August 25, 2022 10:23 AM
To: Sally Thompson-Iritani <sti2@uw.edu>
Cc: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: RE: OLAW Case A3464-11Z

Good afternoon Dr. Thompson-Iritani,

Thank you for the update and your extension is granted. We look forward to receiving your report on Sept. 16, 2022.

Best,
Devora

Devora McCoy, BS, MBA
Program Analyst
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
301-435-2390

From: Sally Thompson-Iritani <sti2@uw.edu>
Sent: Thursday, August 25, 2022 1:04 PM
To: McCoy, Devora (NIH/OD) [E] <devora.mccoy@nih.gov>

Cc: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>; Jane Sullivan <jmsull@uw.edu>; Office of Animal Welfare <oawdirector@uw.edu>

Subject: [EXTERNAL] RE: OLAW Case A3464-11Z

Hello Devora –

We would like to request an extension to Sept. 16, 2022 for official response. Please let us know if there are any concerns.

Thank you -

Sally Thompson-Iritani, DVM/PhD, CPIA, CCFP
Asst. Vice Provost, Animal Care, Outreach & 3Rs
Clinical Associate Professor, DEOHS, SPH
University of Washington, Seattle, WA
Sti2@uw.edu | (b) (6)

From: McCoy, Devora (NIH/OD) [E] <devora.mccoy@nih.gov>

Sent: Friday, July 15, 2022 11:04 AM

To: Sally Thompson-Iritani <sti2@uw.edu>

Cc: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>; Jane Sullivan <jmsull@uw.edu>

Subject: RE: OLAW Case A3464-11Z

Thank you Dr. Thompson-Iritani. We look forward to receiving your response.

Take care,
Devora

Devora McCoy, BS, MBA
Program Analyst
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
301-435-2390

From: Sally Thompson-Iritani <sti2@uw.edu>

Sent: Friday, July 15, 2022 1:54 PM

To: McCoy, Devora (NIH/OD) [E] <devora.mccoy@nih.gov>

Cc: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>; Jane Sullivan <jmsull@uw.edu>

Subject: [EXTERNAL] RE: OLAW Case A3464-11Z

Hi Devora -

We will follow up and respond by Aug. 31, 2022.

Thank you -

Sally Thompson-Iritani, DVM/PhD, CPIA, CCFP
Asst. Vice Provost, Animal Care, Outreach & 3Rs
Clinical Associate Professor, DEOHS, SPH
University of Washington, Seattle, WA
Sti2@uw.edu | (b) (6)

From: McCoy, Devora (NIH/OD) [E] <devora.mccoy@nih.gov>
Sent: Friday, July 15, 2022 10:40 AM
To: Sally Thompson-Iritani <sti2@uw.edu>
Cc: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>; Jane Sullivan <jmsull@uw.edu>
Subject: OLAW Case A3464-11Z

Good afternoon Dr. Thompson-Iritani,

Please see the attached investigative report along with supplemental information from Dr. Tubbs' regarding allegations of noncompliance. If you have any questions, feel free to contact us by phone or by e-mail.

Best,
Devora

Devora McCoy, BS, MBA
Program Analyst
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DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare
6700B Rockledge Drive, Suite 2500, MSC 6910
Bethesda, Maryland 20892-6910
Home Page: <http://grants.nih.gov/grants/olaw/olaw.htm>

FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare
6700B Rockledge Drive, Suite 2500
Bethesda, Maryland 20817
Telephone: (301) 496-7163
Facsimile: (301) 480-3387

July 15, 2022

Re: Animal Welfare Assurance
A3464-01 [OLAW Case 11Z]

Sally Thompson-Iritani, DVM, PhD, CPIA, CCFP
Associate Vice Provost
University of Washington
4000 15th Ave NE- Box 357330
Seattle, WA 98195

Dear Dr. Thompson-Iritani,

The Office of Laboratory Animal Welfare (OLAW) has received from People for the Ethical Treatment of Animals (PETA) allegations of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals and the provisions of the *Guide for The Care and Use of Laboratory Animals* at the University of Washington (UW) and the affiliated Washington National Primate Research Center (WaNPRC) regarding sites in Washington, Arizona, and Louisiana. PETA has provided necropsy and pathology reports (see attached) to OLAW for review. Following OLAW's review of these documents, it appears that the incidents qualified for reporting under PHS Policy IV.F.3, NIH Guide Notice NOT-OD-05-034, and per your commitment to do so in your Animal Welfare Assurance.

Allegation #1: The letter states WaNPRC has failed to ensure that the environment infants are born into is safe and healthy. It is stated that WaNPRC has not taken meaningful measures to prevent, control, or diagnose the etiology of illnesses that caused severe suffering and death in animals. Twenty-five pathology reports regarding infant macaques were noted in the letter, and OLAW reviewed incidents dated between January 2019 through November 2021. Eleven of those pathology reports described animals found dead and ten reports did not describe an etiologic diagnosis, according to the letter received from PETA. Between May 11, 2021 and July 1, 2021, two infants were found dead, two required euthanasia, and one animal deteriorated due to poor maternal handling. *Regarding these findings, please state whether a root cause analysis was conducted to determine if the above incidents were related. Please describe the program for monitoring animals, particularly infants in primate colonies and whether additional post-mortem evaluations and other diagnostic procedures are performed to determine trends in colony health.*

It is also stated while primates at WaNPRC's Mesa facility routinely undergo screening for Coccidiosis, there is a failure to conduct comprehensive necropsies/histopathology, PCR, cultures, etc. The letter refers to the diagnostic laboratory necropsy report dated May 5, 2019, which describes an infant macaque found dead and the dam as lethargic with diarrhea. The letter notes a fecal sample was collected from the dam, but not included in the report. A necropsy report dated June 20, 2021, stated a female macaque collapsed in her enclosure and was euthanized after her condition did not improve with emergency treatment. Ten days later, another pigtailed macaque in the same enclosure became ill, and did not improve with treatment and ultimately died. *Regarding these findings, please state whether a root cause analysis was conducted to determine if the above incidents were related.*

Allegation #2: The letter states dozens of necropsy reports note that histological evaluation was not performed, and PETA cites these reports as a failure to fully investigate cause of death. Seven of ten of those reports are dated within the review period of OLAW (2019-2021). *Please clarify if these animals were euthanized per protocol (i.e., study endpoint) or due to animal health/welfare concerns. Please provide the justification for not performing histology regarding these reports.*

Please provide a summary of the steps taken upon finding a deceased nonhuman primate including all post-mortem evaluations, colony health statistics, changes in preventive medicine, and other relevant preventive steps taken.

Allegation #3: PETA states there was a failure to observe surgeries/procedures which resulted in the discovery of foreign bodies in macaques. The letter states surgical sponges, syringe needles, and catheters are examples of foreign bodies detected in animals. Four reports were highlighted regarding this matter. *Please clarify whether the animals associated with these reports were euthanized based on study endpoints or due to animal welfare concerns, especially those linked to the discovery of foreign bodies. Please describe the procedures/processes in place to mitigate the likelihood of foreign bodies occurring in animal models.*

Allegation #4: It is stated that there has been a failure to perform daily observation of animals to assess health and well-being and/or failure to ensure that only compatible monkeys are housed together. Eight reports were highlighted and described missing fingertips, ears, etc. in the necropsy reports. The letter states there was no indication that these injuries had been previously observed by husbandry or veterinary staff. *Please describe how daily health observations of animals are documented? Please describe how chronic conditions such as missing fingers, fingertips, etc. are documented and recorded in medical records. How are research, husbandry, and veterinary staff notified when an animal has been identified with a chronic condition? Are trained behaviorists actively involved in evaluating compatibility prior to establishing social groups? Are records being kept regarding primate interactions, aggression, affiliative behavior, and composition of the groups?*

Allegation #5: The letter states infants at WaNPRC are increasingly dying from traumatic injuries received in breeding corrals and home cages. Multiple necropsy reports are cited as examples regarding this allegation. These reports include descriptions of infant deaths due to trauma from cage mates, dams, etc. *Please describe the process for determination of female macaques identified as qualified for becoming potential breeders, processes in place to monitor and establish successful social structures (i.e., compatible breeding pairs, compatible social groups, etc.) among primate colonies.*

Please instruct the IACUC, avoiding any conflict of interest, to send a report, signed by you as the Institutional Official, to the following OLAW email inbox: OLAWdco@od.nih.gov. Please have the IACUC consider if any of these occurrences represent programmatic failures. Please also include information regarding any PHS/NSF/DHHS funding of activities related to the occurrences, including grant or contract numbers. If other reportable non-compliances have occurred during this period, please also include them with the report.

We appreciate your cooperation and ask that you please provide the requested information **by August 31, 2022**. Please contact me if I can be of assistance at jacquelyn.tubbs@nih.gov.

Sincerely,

Jacquelyn
T. Tubbs -S

Digitally signed by
Jacquelyn T. Tubbs -S
Date: 2022.07.15
11:39:20 -04'00'

Jacquelyn Tubbs, DVM, DACLAM
Senior Animal Welfare Program Specialist
Division of Compliance Oversight
Office of Laboratory Animal Welfare

enclosures
cc: IACUC Contact

McCoy, Devora (NIH/OD) [E]

From: McCoy, Devora (NIH/OD) [E]
Sent: Friday, July 15, 2022 2:04 PM
To: Sally Thompson-Iritani
Cc: OLAW Division of Compliance Oversight (NIH/OD); Jane Sullivan
Subject: RE: OLAW Case A3464-11Z

Thank you Dr. Thompson-Iritani. We look forward to receiving your response.

Take care,
Devora

Devora McCoy, BS, MBA
Program Analyst
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
301-435-2390

From: Sally Thompson-Iritani <sti2@uw.edu>
Sent: Friday, July 15, 2022 1:54 PM
To: McCoy, Devora (NIH/OD) [E] <devora.mccoy@nih.gov>
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Subject: [EXTERNAL] RE: OLAW Case A3464-11Z

Hi Devora -

We will follow up and respond by Aug. 31, 2022.

Thank you -

Sally Thompson-Iritani, DVM/PhD, CPIA, CCFP
Asst. Vice Provost, Animal Care, Outreach & 3Rs
Clinical Associate Professor, DEOHS, SPH
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Subject: OLAW Case A3464-11Z

Good afternoon Dr. Thompson-Iritani,

Please see the attached investigative report along with supplemental information from Dr. Tubbs' regarding allegations of noncompliance. If you have any questions, feel free to contact us by phone or by e-mail.

Best,
Devora

Devora McCoy, BS, MBA
Program Analyst
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National Institutes of Health
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A3464-112

AN INTERNATIONAL ORGANIZATION DEDICATED TO PROTECTING THE RIGHTS OF ALL ANIMALS

PETA



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),¹ 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.

¹Curiously, 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.

PEOPLE FOR
THE ETHICAL
TREATMENT
OF ANIMALS

Washington
1536 16th St. N.W.
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202-483-PETA

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323-644-PETA

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Entities:

- * PETA Asia
- * PETA India
- * PETA France
- * PETA Australia
- * PETA Germany
- * PETA Switzerland
- * PETA Netherlands
- * PETA Foundation (U.K.)

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 well-being, 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,² 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.³

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.⁴
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.⁵
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.⁶
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.⁷
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.⁸

² 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

³ [Arizona Republic wins National Headliner Award for monkey farm series \(azcentral.com\)](https://www.azcentral.com/story/news/local/arizona-republic-wins-national-headliner-award-for-monkey-farm-series/2022/04/15/arizona-republic-wins-national-headliner-award-for-monkey-farm-series/7000000001/)

⁴ Ex. 1

⁵ Ex. 2

⁶ Ex. 3

⁷ Ex. 4

⁸ 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.¹⁰
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.¹¹
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.¹³
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

⁹ Ex. 6

¹⁰ Ex. 7

¹¹ Ex. 8

¹² Ex. 9

¹³ Ex. 10

¹⁴ 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 5th 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.¹⁵

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.¹⁶
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.”¹⁷
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.¹⁹
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.²⁰

¹⁵ Ex. 12

¹⁶ Ex. 13

¹⁷ Ex. 14

¹⁸ Ex. 15

¹⁹ Ex. 16

²⁰ 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.²¹
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.²²
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.²³
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.²⁴
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.²⁵
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

²¹ Ex. 18

²² Ex. 19

²³ Ex. 20

²⁴ Ex. 21

²⁵ Ex. 22

²⁶ 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.**²⁷
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.²⁸

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.

Coccidioidomycosis has been detected in WaNPRC monkeys.²⁹ 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 Coccidioidomycosis 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*")—yet fail to conduct comprehensive necropsies/histopathologies, 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

²⁷ Ex. 24

²⁸ Ex. 25

²⁹ Ex. 26

³⁰ Ex. 27

pigtailed macaque, J06251, was found collapsed in her enclosure; emergency treatment failed to improve her condition and she was euthanized.³¹ 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.³² 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.”³³

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—P51OD010425 and U42OD011123—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.

1. 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.”³⁴
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

³¹ Ex. 28

³² Ex. 29

³³ Ex. 30

³⁴ 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.³⁵

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.”³⁶
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.³⁷
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.”³⁸
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.”³⁹
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.”⁴¹
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

³⁵ Ex. 32

³⁶ Ex. 33

³⁷ Ex. 34

³⁸ Ex. 35

³⁹ Ex. 36

⁴⁰ Ex. 37

⁴¹ Ex. 38

clinical history noted abnormal blood, and the necropsy report noted moderate, bilateral, caudal hydrocephalus. However, histology was not requested.⁴²

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."⁴⁵
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

⁴² Ex. 39

⁴³ Ex. 40

⁴⁴ Ex. 41

⁴⁵ Ex. 42

⁴⁶ 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.⁴⁸
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.⁴⁹
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.⁵⁰
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

⁴⁷ Ex. 44

⁴⁸ Ex. 45

⁴⁹ Ex. 46

⁵⁰ Ex. 47

was partially missing and healed over; and that multiple digits were missing and healed over.⁵¹

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.⁵²
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.⁵⁴
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.⁵⁵

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.

⁵¹ Ex. 48

⁵² Ex. 49

⁵³ Ex. 50

⁵⁴ Ex. 51

⁵⁵ 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.⁶³
9. On April 17, 2021, at 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

⁵⁶ Ex. 53

⁵⁷ Ex. 54

⁵⁸ Ex. 55

⁵⁹ Ex. 56

⁶⁰ Ex. 57

⁶¹ Ex. 58

⁶² Ex. 59

⁶³ Ex. 60

multiple skull fractures and broken ribs, and the suspected cause of death was traumatic brain injury.⁶⁴

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.⁶⁷

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.⁶⁸ In the wild, pigtailed macaques live in large multi-male, multi-female groups with strong female bonds and stable matriline. 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 (b) (6) and WaNPRC (b) (6) served as

⁶⁴ Ex. 61

⁶⁵ Ex. 62

⁶⁶ Ex. 63

⁶⁷ Ex. 64

⁶⁸ 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 (b) (6) Thank you.

Sincerely,

(b) (6)

Ward, Joan (NIH/OD) [E]

From: Morse, Brent (NIH/OD) [E]
Sent: Monday, May 16, 2022 9:14 AM
To: Ward, Joan (NIH/OD) [E]
Subject: FW: University of Washington -Primate Research Center Apparent PHS violations

Here is my acknowledgement.

Brent C. Morse, DVM, DACLAM
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health

From: Morse, Brent (NIH/OD) [E]
Sent: Monday, May 16, 2022 9:11 AM
To: (b) (6)
Subject: RE: University of Washington -Primate Research Center Apparent PHS violations

Dear (b) (6)

This is to confirm that OLAW has received PETA's allegations regarding the WaNPRC and attached 15-page and 190-page documents. We will review the information and take any required action.

Sincerely, Brent Morse

Brent C. Morse, DVM, DACLAM
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health

From: (b) (6)
Sent: Tuesday, May 10, 2022 11:45 AM
To: Morse, Brent (NIH/OD) [E] <morseb@mail.nih.gov>
Cc: (b) (6)
Subject: [EXTERNAL] University of Washington -Primate Research Center Apparent PHS violations

Good morning Dr. Brent,

In response to a Washington public records request submitted to the University of Washington in October 2021, requesting all Washington National Primate Research Center (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 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. It appears to us that UW/WaNPRC failed to comply with the Public Health Service Policy on Humane Care and Use of Laboratory Animals and the Guide for the Care and Use of Laboratory Animals.

None of the 59 incidents included in this complaint have been self-reported to the USDA or OLAW. None of these incidents has been reported during the monthly IACUC meetings at which UW's Attending Veterinarian and WaNPRC's Site 002 veterinarians are required to describe adverse events. WaNPRC pathologist Robert Murnane and WaNPRC veterinarian Charlotte Hotchkiss served as 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 (b) (6)

Given the size of the attachments can you please confirm that you have received this complaint and can access the attached pdfs?

(b) (6)