



Inspection Report

University of Washington
Box 357160
Seattle, WA 98195

Customer ID: **1016**

Certificate: **91-R-0001**

Site: 001

UNIVERSITY OF WASHINGTON

Type: ROUTINE INSPECTION

Date: 08-JUL-2025

2.31(e)(3)

Repeat

Institutional Animal Care and Use Committee (IACUC).

Six rhesus macaques assigned to a protocol had undergone more imaging procedures (MRI/PET) between July 2022 and December 2023 (MRI/PET) than were described in the approved IACUC protocol at the time. The approved protocol at the time stated that at baseline animals undergo "magnetic resonance imaging (MRI) procedure, at least 2 weeks recovery, baseline positron emission tomography imaging (PET) procedure". Following the experimental injection, the approved protocol described "quarterly PET scans for the duration of the experimental time (1-2 years)". The approved protocol did not describe post-injection MRI. IACUC issued a letter of reprimand at the January 2025 meeting.

Over the last 3 years, more non-human primates were used for a viral vector study and MRI's than were approved on the protocol. The approved viral vector protocol includes two separate experiments, with 12 animals in Experiment 1 and 10 animals for Experiment 2. Exceeding the protocol, 16 animals were used in Experiment 1 and 12/16 received an MRI prior to viral vector injection and 6 animals were used in Experiment 2. While the protocol is approved for MRI in the context of viral vector work on Experiment 2, MRI was not approved in the viral vector efficacy testing in Experiment 1. IACUC issued a letter of counsel at the May 2025 meeting.

During the week of January 20th, 2025, one rhesus macaque was administered a combined dose of cetuximab at 8mg/kg that exceeded the approved dose in the protocol of 5 mg/kg in a week, divided and no less than 2 days apart. Cetuximab is a monoclonal antibody medication administered as a safety switch in the event of an adverse response (cytokine storm) to the genetically modified CAR T cells. According to the facility, there was no apparent animal welfare impact from administration of the elevated dose, although the animal was subsequently euthanized due to complications from the CAR T cell therapy, which was anticipated in the protocol & IACUC sent a letter of acknowledgement at the March 2025 meeting.

Ten pigtail macaques received incorrect strain of influenza A virus From April of 2022 to March of 2024, which was suspected by the research team after an early euthanasia of one animal under veterinary care at day 3 instead of 5 and subsequent genotyping of the flu strains administered. The delay in reporting was attributed to the development of a new PCR assay to distinguish between the strains and probable human error was identified as the cause & IACUC sent a letter of acknowledgement in November 2024 meeting.

Prepared By: KATHARINE FRANK

USDA, APHIS, Animal Care

Date:

04-AUG-2025

Title: VETERINARY MEDICAL
OFFICER

Received by Title: IACUC Representative

Date:

04-AUG-2025



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All the procedures to which animals are subjected must be included in a complete description of the proposed use of the animals. It is essential that this information be included in the protocol submitted to the IACUC for review to ensure the judicious and humane use of the animals.

Corrected at the time of inspection, 8 July 2025

2.33(a)(2) Critical

Attending veterinarian and adequate veterinary care.

The Attending Veterinarian (AV) submitted a minority report attached to the semi-annual report to the IO in January 2025 regarding the removal of a letter of counsel to the PI, where the end result was the death of a geriatric nonhuman primate that was shipped cross country without following established shipping or IACUC procedures. The IACUC had originally issued a letter of counsel to the PI (Sep 24 meeting minutes), but rescinded it and the AV disagreed, because the situation had a serious impact on the welfare of one of the animals transported. The facility shall ensure that the AV has the appropriate authority to ensure the provision of adequate veterinary care and oversee the adequacy of other aspects of animal care and use.

Corrected at the time of inspection, 8 July 2025

2.33(b)(3)

Attending veterinarian and adequate veterinary care.

At the June 2024 IACUC meeting, an adverse event (Incident #2) was reported to the committee from August 2023 in which, during an intracranial injection surgery on a non-human primate, there was a software malfunction that caused the robotic arm holding the cannula to perform small uninstructed movements. The surgery was immediately suspended, the surgery site was closed, and the animal was allowed to recover from anesthesia. During recovery the animal had a seizure that responded to diazepam, and as recovery progressed, it was noted that the animal did not have full function of the left side of its body. Symptoms improved over the subsequent 2-3 weeks. The lab requested a 2nd surgery to complete the injections, at which time they were informed that they needed to submit an amendment to the protocol. An amendment was submitted and was approved by the IACUC to add the option to perform a 2nd surgery if an unexpected event such as an equipment failure precluded them from completing a planned surgery.

During the review of this amendment, neither the specifics of the robot arm malfunction nor the animal's clinical condition were reported to OAW, the AV, or the IACUC. The second surgery was performed approximately 3 weeks after the 1st surgery, after the amendment was approved. While there was no malfunction of the robotic arm during that 2nd surgery, the animal did not recover from anesthesia and was euthanized. Gross necropsy revealed an approximately 3cm diameter blood clot at the brain stem, oriented to the right side, and hemorrhage along the base of the brain with congested ventral cerebral vessels and submeningeal hemorrhage. The location of the hemorrhage suggested that it was likely secondary to injections, but did not discriminate between the first surgery with the malfunctioning robotic arm or the second surgery. The Principal Investigator (PI) responded to the IACUC that it was assumed that it was the clinical vet's responsibility, not the PI. The IACUC identified this as a programmatic gap that needs to be addressed. Under the Animal Welfare Act, the PI is responsible for the implementation of research involving animals, especially communicating unexpected adverse events that impact the welfare of animals used in their research.

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Animal Welfare Act requires an effective mechanism of direct and frequent communication so that timely and accurate information on problems of health and well-being of the animals is conveyed to the Attending Veterinarian.

Correct by 21 August 2025

3.75(c)(2)

Housing facilities, general.

Three rooms have loose chipping paint along the ceiling directly above enclosures inhabited by Pigtail and Rhesus macaques with exposed concrete rendering this area difficult to effectively clean and sanitize. Surfaces in non-human primate housing facilities require regular maintenance to keep them in good repair, to allow them to be readily cleaned and sanitized and to protect the animals from injury. All surfaces of non-human primate housing facilities must be maintained on a regular basis.

Correct by 8 August 2025

3.75(e)

Housing facilities, general.

In the nonhuman primate lab area/kitchen, clippers, clipper oil and bottle of cleaner was on the counter intermingled with cutting boards for preparing food items (also stored in the area), as well as a variety of chemicals under the sink. Chemicals could contaminate food or food contact surfaces, and should not be on the counter. Substances that are toxic to the nonhuman primates but that are required for normal husbandry practices must not be stored in food storage and preparation areas, but may be stored in cabinets in the animal areas.

Correct by 8 August 2025

This inspection and exit interview were conducted with the IACUC and facility staff.

Additional Inspectors:

Darren Rausch, VETERINARY MEDICAL OFFICER

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Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
1016	91-R-0001	001	UNIVERSITY OF WASHINGTON	08-JUL-2025

Count	Scientific Name	Common Name
000011	<i>Macaca fascicularis</i>	CRAB-EATING MACAQUE / CYNOMOLGUS MONKEY
000122	<i>Macaca mulatta</i>	RHESUS MACAQUE
000254	<i>Macaca nemestrina</i>	PIG-TAILED MACAQUE
000006	<i>Canis familiaris</i>	DOG ADULT
000009	<i>Meriones unguiculatus</i>	MONGOLIAN GERBIL
000017	<i>Mustela putorius furo</i>	DOMESTIC FERRET
000054	<i>Oryctolagus cuniculus</i>	DOMESTIC RABBIT / EUROPEAN RABBIT
000002	<i>Calypte anna</i>	ANNA'S HUMMINGBIRD
000002	<i>Sus scrofa domestica</i>	DOMESTIC PIG / POTBELLY PIG / MICRO PIG
000477	Total	