### AN INTERNATIONAL ORGANIZATION DEDICATED TO PROTECTING THE RIGHTS OF ALL ANIMALS

January 29, 2024

Brent C. Morse, D.V.M. Director Division of Compliance Oversight Office of Laboratory Animal Welfare National Institutes of Health

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

Dear Dr. Morse:

I'm writing on behalf of People for the Ethical Treatment of Animals— PETA entities have more than 9 million members and supporters globally to request that your office investigate possible noncompliance 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) related to the treatment of animals at Wake Forest University (WFU; Animal Welfare Assurance ID D16-00248).

According to a December 19, 2023, U.S. Department of Agriculture (USDA) inspection report for WFU, an investigation by the Institutional Animal Care and Use Committee (IACUC) documented two incidents in which staff performed off-protocol activities on primates. On three occasions in May 2023, staff conducted unapproved blood draws on three primates. On two occasions in April and May 2023, staff gave an unapproved substance to three primates. The report notes, "Performing activities not covered by IACUC-approved protocols can result in harm or death to the impacted animals."

Additionally, the inspection report details that an IACUC investigation documented that an investigator engaged in two separate actions that interfered with the authority of the attending veterinarian (AV). The investigator intentionally excluded four out of 20 rhesus macaques from a request from AV staff "regarding possible animal exposure to a contaminated substance." The investigator also instructed staff to flush the IV catheters of two primates "immediately prior to sampling by AV staff, with the apparent intent of obscuring culture results." The report notes, "Intentionally interfering with the authority of the AV can lead to harm or death of the impacted animals."

Furthermore, the inspection report provides that an IACUC investigation documented three incidents in which staff failed to communicate daily observations regarding the health and well-being of animals to AV staff. In October and November 2022, an investigator didn't appropriately report to AV staff when they observed an exposed subcutaneous vascular access port on a primate for four days. Rather, another veterinarian reported the exposed port. In April 2023, an investigator gave an off-protocol drug to a macaque,



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who then became "excessively hypothermic with marked sedation." The incident wasn't reported to AV staff in a timely manner. In May 2023, staff put a macaque in the wrong enclosure with another primate and the macaque sustained injuries. Staff didn't report the incident to AV staff, and the injuries weren't discovered until the next morning. The animal required surgery to address the injuries, a 4-centimeter-deep laceration on the chest and a 1-centimeter laceration on the head. The report notes, "Not reporting daily observations regarding animal health and welfare concerns can put the animals' health and lives at risk."

The issues raised in the USDA's inspection report for WFU—the failures of the IACUC and the AV to ensure and monitor adherence to approved protocols and the administration of appropriate veterinary care—also indicate noncompliance with PHS Policy and the Guide.

The Guide instructs that an institution's animal care and use program must include adequate policies, procedures, and practices "to achieve the humane care and use of animals in the laboratory and throughout the institution" (p. 6). Additionally, the institution must maintain an environment in which the IACUC can "function successfully to carry out its responsibilities" and the institution is responsible for ensuring that "IACUC members are provided with training opportunities to understand their work and role" (pp. 6 and 17). Furthermore, the IACUC is responsible for "assessment and oversight" of the institution and should have "sufficient authority and resources (e.g., staff, training, computers, and related equipment) to fulfill this responsibility" (pp. 14–15).

The Guide also states that the AV "is responsible for the health and well-being of all laboratory animals used at the institution. The institution must provide the AV with sufficient authority, including access to all animals, and resources to manage the program of veterinary care" (p. 14).

In addition to establishing this responsibility of the IACUC and the AV, the Guide addresses the importance of the proper training for staff involved in animal care and surgeries. It states, "Personnel caring for animals should be appropriately trained ... and the institution should provide for formal and/or on-the-job training to facilitate effective implementation of the Program and the humane care and use of animals. Staff should receive training and/or have the experience to complete the tasks for which they are responsible" (p. 16). Furthermore, "[t]he institution should provide appropriate education and training to members of research teams—including principal investigators, study directors, research technicians, postdoctoral fellows, students, and visiting scientists—to ensure that they have the necessary knowledge and expertise for the specific animal procedures proposed and the species used" (pp. 16–17).

The IACUC also has the responsibility—under federal law, regulations, and policies—to continually monitor the use and care of animals (p. 33). Post-approval monitoring includes "observation of animals by animal care, veterinary, and IACUC staff and members" (p. 33).

The failures of the WFU IACUC and the AV to ensure and monitor that staff followed approved protocols and reported adverse events—leading to multiple incidents in which animals were harmed and didn't receive prompt veterinary care—illustrate a complete breakdown in the institution's animal care and use program. The actions of WFU staff are not only negligent but also constitute intentional interference with program guidelines.

In FY 2023 alone, the National Institutes of Health (NIH) awarded WFU almost \$8 million and WFU's Division of Public Health Sciences over \$151 million. Such funding should be able to ensure that a program functions properly, but WFU has proved that it can't meet even basic animal welfare requirements, regardless of what resources it has—and so WFU should no longer receive NIH funding and its Animal Welfare Assurance should be revoked.

We urge you to investigate the concerns summarized in this letter and to take swift and decisive action against WFU. Thank you for your time and consideration.

Sincerely,

and

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