

April 07, 2025

Richard J. Hodes, M.D. Director National Institute on Aging

Noni Byrnes, Ph.D. Director Center for Scientific Review

Sheila Garrity, J.D., M.P.H., M.B.A. Director Office of Research Integrity

Via e-mail: <a href="mailto:hodesr@31.nia.nih.gov">hodesr@31.nia.nih.gov</a>; <a href="mailto:byrnesn@mail.nih.gov">byrnesn@mail.nih.gov</a>; <a href="mailto:AskORI@hhs.gov">AskORI@hhs.gov</a>

Dear Dr. Hodes, Dr. Byrnes, and Ms. Garrity:

I am writing to formally request that the National Institutes of Aging (NIA) take immediate action to recover funding associated with the ongoing, more than four-million dollar R01AG069227 Disambiguating Natural Aging from Alzheimer's Disease through Changes in Oral Neuromechanics grant awarded to the University of Washington (UW) and led by principal investigator (PI) Fritzie Arce-McShane. Given that Arce-McShane's research has been halted for months due to serious protocol violations and regulatory actions, it is inappropriate for UW to continue accepting taxpayer funding from the National Institutes of Health for work that is not being conducted.

Arce-McShane's Institutional Animal Care and Use Committee (IACUC) protocol was halted on August 29, 2024, in response to serious protocol violations. Her previously approved 3-year protocol lapsed in January 2025, and on March 20, 2025, the UW IACUC voted *not* to approve her new triennial protocol, effectively terminating any legal authorization for her animal research. IACUC members raised multiple concerns, including whether there was adequate scientific justification for such a grueling experiment and the failure of Arce-McShane's lab to refine surgical techniques and the experimental hardware design to increase the likelihood of successfully gathering data from the monkeys assigned to her study. A veterinarian described how, in previous surgeries, the skin on the head of an elderly macaque eroded, exposing the wires connected to electrodes implanted in the animal's brain. The IACUC concluded that no appropriate hardware is currently available to prevent this problem from happening again.

Despite this, UW has continued to accept NIH \$1,267,577 in taxpayer funding for this project, even though no approved animal research has been conducted since at least August 2024.

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Furthermore, recent federal actions underscore the gravity of Arce-McShane's misconduct. On March 10, 2025, the United States Department of Agriculture (USDA) issued an Official Warning Notice of Alleged Violation to UW, citing her violations of the Animal Welfare Act.

UW has known for at least seven months that Arce-McShane has been unable to conduct the animal research for which she was awarded NIH funding. Even more concerning is that <a href="Year 5 funding of R01AG069227">Year 5 funding of R01AG069227</a> began on June 1, 2024—before her protocol suspension but after documented violations had already occurred. The USDA Notice of Alleged Violations states that Arce-McShane's breaches of her IACUC protocol took place "Between May 2024 and June 2024." This means that UW accepted Year 5 funding despite knowing that Arce-McShane was not in compliance with her approved research protocol and had already engaged in serious ethical and legal violations.

<u>Specifically, UW was aware</u> that between May 14 and June 26, 2024, Arce-McShane repeatedly exposed an adult male rhesus macaque to radiation via videofluoroscopy, violating her IACUC protocol. The protocol required at least 48 hours between exposures, yet the monkey was subjected to radiation for three consecutive days in four out of five weeks. By June 20, the monkey showed signs of radiation toxicity—abnormal pigmentation and dry, flaky facial skin—but Arce-McShane did not disclose the protocol violations to UW veterinary staff, delaying critical intervention.

On June 27, after another radiation exposure, the monkey exhibited severe symptoms—lethargy, loss of appetite, and pain while eating—prompting veterinary staff intervention. Only then did Arce-McShane admit to exceeding the approved radiation limits. Despite extensive clinical care, the monkey's condition deteriorated, developing facial swelling, redness, eye and nasal discharge, and severe discomfort. The animal required euthanasia on September 4, 2024.

Further IACUC reviews in August and September 2024 uncovered additional violations, including failure to use required protective goggles for the elderly monkey and the improper administration of medication, exacerbating the animal's suffering.

It is fraudulent for UW to continue receiving more than \$1 million per year in NIH funds for research that is not being conducted and, worse, was carried out in a manner that appears to have violated both federal and state law. NIH policies require grantee institutions to adhere to ethical research practices, and the evidence overwhelmingly demonstrates that UW has failed to uphold these standards in connection with this grant.

Additionally, Arce-McShane admitted to the IACUC that since arriving at UW in 2021, her progress on the project has been extremely slow, citing difficulties in setting up her laboratory and hiring qualified staff. Given that she has apparently failed to advance the planned research for years—making it unlikely that she has produced work commensurate with the more than \$4 million in NIH taxpayer funding—and that her project has been marred by protocol violations, questionable scientific justification, failure to refine methods, misleading veterinary staff, and regulatory intervention, NIH should not merely seek to recover the most recent year of funding but should demand a full return of all grant money awarded to the University of Washington for this project.

I urge the NIH to take immediate steps to reclaim all remaining grant funds and ensure that taxpayer dollars are not used to support research that has been suspended due to misconduct. Given the serious misconduct associated with this project, I urge the NIH to consider barring Arce-McShane

from receiving any future funding as a principal investigator on NIH-supported research. Please advise on how the NIH intends to proceed regarding this matter.

PETA can provide recordings of the IACUC meetings where Arce-McShane's protocol was discussed to assist with your investigation. I look forward to your prompt response.

Sincerely,

Lisa Jones-Engel, Ph.D.

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Cc: University of Washington Board of Regents <a href="mailto:regents@uw.edu">regents@uw.edu</a>