

March 30, 2022

Deborah Kearse
Director
Division of Program Integrity
Office of Management Assessment
National Institutes of Health

Re: DPI Case Number 2021-017

Via e-mail: deborah.kearse@nih.gov

Dear Director Kearse:

Thank you in advance for your time. 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 share additional disturbing information to supplement our complaint dated February 17, 2021¹—which the Division of Program Integrity (DPI) assigned case number 2021-017—and our related complaint dated November 18, 2021.²

Based on the evidence presented below, we urge your office to investigate, and, if noncompliance is corroborated, ensure that National Institutes of Health (NIH)—funded experimenters adhere to federal mandates to reduce and/or replace the use of animals in experiments and to stop wasting public resources to support activities related to the acquisition, breeding, confinement, maintenance, repopulation, and/or experimentation of animals deemed by experimenters to be extraneous, nonessential, noncritical, or described using similar terminology.

History of PETA's Complaints Regarding Euthanasia of Animals Deemed Extraneous

On June 15, 2020, we submitted a detailed complaint to the U.S. Department of Health and Human Services Office of Inspector General (HHS-OIG) regarding the troubling problem of universities across the country deeming many of their NIH-funded experiments—and the animals used in them—extraneous, nonessential, or noncritical or describing them using similar terminology in response to the

¹People for the Ethical Treatment of Animals. Letter to NIH OMA. February 17, 2021. Accessed March 10, 2022. https://www.peta.org/wp-content/uploads/2021/02/2021-02-17_Follow_up_letter_to_OMA_HHS.pdf
²People for the Ethical Treatment of Animals. Letter to NIH OMA/DPI. November 18, 2021. Accessed March 10, 2022. https://www.peta.org/wp-content/uploads/2022/03/2021-11-18 Complaint-update NIH-OMA_DPI.pdf

PEOPLE FOR THE ETHICAL TREATMENT OF ANIMALS

Washington

1536 16th St. N.W. Washington, DC 20036 202-483-PETA

Los Angeles

2154 W. Sunset Blvd. Los Angeles, CA 90026 323-644-PETA

Norfolk

501 Front St. Norfolk, VA 23510 757-622-PETA

Info@peta.org PETA.org

Entities:

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

COVID-19 pandemic, resulting in the euthanasia of such animals confined in laboratories and a massive waste of taxpayer funds.³

On June 23, 2020, we were notified by HHS-OIG Public Affairs that our complaint had been forwarded to the then-director of NIH's Office of Management Assessment (OMA), Michael D. Shannon,⁴ to which we received no reply. On February 17, 2021, we submitted a new complaint⁵ addressed to Acting Director of OMA Meredith Stein, CPA, which was assigned case number 2021-017 by NIH's Division of Program Integrity on February 17, 2021. We then acquired additional evidence of animals being deemed extraneous and euthanized in NIH-funded experiments, which we detailed in a letter to you on November 18, 2021,⁶ to supplement the aforementioned complaint.

New Information That Supplements Our Complaints

Experimenters affiliated with the NIH-funded institutions mentioned below have acknowledged that euthanasia of animals deemed extraneous to the experiments occurred in response to the COVID-19 pandemic, similar to the numerous institutions we detailed in our original and supplementary complaints:

• University of Connecticut (UConn)

Per its COVID-19 guidance, UConn notified its staff that "[1]abs and research programs should continue to have and refine plans to immediately halt or ramp down research activities, if required." A Research Shut Down Notice issued by UConn on March 23, 2020, directed research staff to "immediately reduce animal numbers and number of cages." In addition, the "COVID-19 Research Ramp Down" letter issued by the Office of the Vice President for Research at UConn notified its staff that "[r]esearchers will begin immediately to ramp down research activities, including laboratory, animal, and non-therapeutic human subjects research." As a result, two rabbits assigned to UConn experimenter Harvey Swadlow's protocol titled "Thalamortical Processing of Visual Information During Alert and Non-Alert Brain States" (NIH project numbers 1R01EY028905-01, 5R01EY028905-02,

³People for the Ethical Treatment of Animals. Request to HHS OIG Regarding COVID-19 Contingency Plans at U.S. Universities. June 15, 2020. Accessed March 10, 2022. https://www.peta.org/wp-content/uploads/2020/06/20-06-15-Request-to-HHS-OIG-regarding-COVID-19-contingency-plans-at-US-universities.pdf

⁴HHS-OIG Public Affairs RE: RE: For HHS OIG, from PETA—re Request for Investigation Into Apparent Waste at NIH and Failure to Reduce/Replace Animal Use. June 23, 2020. Accessed March 10, 2022. https://www.peta.org/wp-content/uploads/2021/02/2020-06-23 For-HHS-OIG-from-PETA-re-request-for-investigation.pdf

⁵People for the Ethical Treatment of Animals. Letter to NIH OMA. February 17, 2021. Accessed March 10, 2022. https://www.peta.org/wp-content/uploads/2021/02/2021-02-17_Follow_up_letter_to_OMA_HHS.pdf
⁶People for the Ethical Treatment of Animals. November 18, 2021. Complaint Update.

https://www.peta.org/wp-content/uploads/2022/02/2021-11-18 Complaint-update NIH-OMA DPI.pdf ⁷UConn. COVID-19 Guidance for the UConn Research Community. Accessed March 10, 2022. https://ovpr.uconn.edu/covid-19-guidance-for-the-uconn-research-community-2-2/

⁸UConn. Research Shut Down Notice. March 22, 2020. Accessed March 10, 2022. Research Shut Down Notice March 23, 2020 | Office of the Vice President for Research (uconn.edu)

⁹UConn. COVID-19 Research Ramp Down. March 17, 2020. Accessed March 10, 2022. https://ovpr.uchc.edu/2020/03/17/covid-19-research-ramp-down/.

5R01EY028905-03, and 5R01EY028905-04)—which received \$1,195,425 from FY2018 to FY2021¹⁰—were euthanized in March 2020.¹¹ This was verified in correspondence with UConn staff released to PETA.¹²

• University of Wisconsin (UW)–Madison

Per its COVID-19 response plan, UW-Madison notified its staff that "[a]ll on-site research activities must be approved by a dean or director, who are directed to only approve essential research, based on their judgement" and that "[r]esearchers should consider reduction or cessation of non-critical animal breeding, including agricultural animals and USDA-covered species." As a result, an estimated two-thirds of a nearly 700-member colony of mice assigned to UW-Madison experimenter Laura Knoll's protocol, "Sexual Development of Toxoplasma in Feline Intestinal Organoids" (NIH project numbers 1R01AI144016-01, 5R01AI144016-02, 5R01AI144016-03, 5R01AI144016-04)—which received \$1,524,195 from the National Institute of Allergy and Infectious Diseases from FY2019 to FY2022 to FY2022

That these laboratories had animals deemed by experimenters to be unnecessary, nonessential, noncritical, extraneous, or other similar terminology in the first place should raise significant red flags. Given the widespread euthanasia of these animals because of COVID-19 at universities across the country and the large amount of NIH funding that these individual institutions receive in research grants, taxpayers should not have to foot the bill for such waste.

Apparent Failure of NIH-Funded Protocols to Reduce and Replace Animal Use The presence of animals deemed unnecessary, nonessential, noncritical, or extraneous in these institutions' laboratories flies in the face of existing regulations to minimize animal use in experiments.

¹⁰NIH. RePORTER. Thalamortical Processing of Visual Information During Alert and Non-Alert Brain States. https://reporter.nih.gov/search/Fwk69-p90k-benm300z4QA/projects

¹¹UConn Animal Services. Individual Animal Health Record. (2020). Accessed March 10, 2022. https://www.peta.org/wp-content/uploads/2022/02/FOIA-20-264 Redacted.pdf.

¹²University of Connecticut. Public Records Request. (2020). Accessed March 10, 2022. https://www.peta.org/wp-content/uploads/2022/02/confirmation-from-UConn.pdf.

¹³University of Wisconsin–Madison. Kaylie Flaugher People for the Ethical Treatment of Animals (PETA) Public Records Request: P001886-092321. Accessed March 10, 2022. https://www.peta.org/wp-content/uploads/2022/01/uw-madison-responsive-records-response-letter.pdf

¹⁴University of Wisconsin–Madison. (2020). Campus Research Activities Update. March 19, 2020. Accessed March 10, 2022. https://news.wisc.edu/campus-research-activities-update/

¹⁵Cima G. Research Delayed, Rodent Populations Reduced During Pandemic. American Veterinary Medical Association. Published April 29, 2020. Accessed March 10, 2022. https://www.avma.org/javma-news/2020-05-15/research-delayed-rodent-populations-reduced-during-pandemic.

¹⁶National Institutes of Health. RePORTER. Sexual Development of Toxoplasma in Feline Intestinal Organoids. Accessed March 10, 2022. https://reporter.nih.gov/search/hZZvR14-7UWc8-IrJu7SFQ/projects
¹⁷University of Wisconsin–Madison. Kaylie Flaugher People for the Ethical Treatment of Animals (PETA) Public Records Request: P001886-092321. Accessed March 10, 2022. https://www.peta.org/wp-content/uploads/2022/01/uw-madison-responsive-records-response-letter.pdf

NIH-supported language to minimize animal use in experiments is present in the Health Research Extension Act of 1985, the NIH Revitalization Act of 1993, the eighth edition of the *Guide for the Care and Use of Laboratory Animals*, and the U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training:

- The Health Research Extension Act of 1985 states, "The Director of NIH shall require each applicant for a grant, contract, or cooperative agreement involving research on animals ... to include in its application or contract proposal ... (1) assurances satisfactory to the Director of NIH that ... (B) scientists, animal technicians, and other personnel involved with animal care, treatment, and use by the applicant have available to them instruction or training in the ... use of research or testing methods that limit the use of animals or limit animal distress" [emphasis added]. 18
- The National Institutes of Health Revitalization Act of 1993 states, "The Director of NIH ... shall prepare a plan ... for the National Institutes of Health to conduct or support research into ... methods of such research and experimentation that reduce the number of animals used in such research" [emphasis added]. 19
- The eighth edition of the Guide for the Care and Use of Laboratory Animals states, "The Guide ... endorses the following principles: consideration of alternatives (in vitro systems, computer simulations, and/or mathematical models) to reduce or replace the use of animals" [emphasis added].²⁰
- The U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training (1985) states, "The animals selected for a procedure should be of an appropriate species and quality and *the minimum number required to obtain valid results*" [emphasis added].²¹

When these institutions' experimenters buy, breed, trap, and/or use animals who at any time—not just during the COVID-19 pandemic—can be deemed extraneous or described using similar terminology, they squander limited research funds, much of which come from taxpayers, and flout the foundational "3Rs" principle of reducing, replacing, and refining the use of animals in experimentation that is enshrined in government regulations and policies.

Under this standard, the number of animals deemed unnecessary, nonessential, noncritical, or extraneous and used in the aforementioned experiments should have been

¹⁸Office of Laboratory Animal Welfare. National Institutes of Health. Health Research Extension Act of 1985, Publ. L. No. 99-158. Accessed March 10, 2022. https://olaw.nih.gov/policies-laws/hrea-1985.htm
¹⁹National Institutes of Health. NIH Revitalization Act of 1993, Publ. L. No. 103-43. Accessed March 10, 2022. https://grants.nih.gov/grants/olaw/pl103-43.pdf

²⁰National Institutes of Health. National Center for Biotechnology Information. National Research Council Committee for the Update of the Guide for the Care and Use of Laboratory Animals. Appendix B: U.S. government principles for the utilization and care of vertebrate animals used in testing, research, and training. Accessed March 10, 2022. https://www.ncbi.nlm.nih.gov/books/NBK54048/

²¹National Institutes of Health. National Center for Biotechnology Information. National Research Council Committee for the Update of the Guide for the Care and Use of Laboratory Animals. Appendix B: U.S. government principles for the utilization and care of vertebrate animals used in testing, research, and training. Accessed March 10, 2022. https://www.ncbi.nlm.nih.gov/books/NBK54048/

zero from the start, since they weren't relevant to the protocols led by these institutions' employees. Also, because taxpayer funds were used to acquire, breed, confine, and/or maintain these animals who were deemed extraneous (or described using similar terminology) and then so readily euthanized and disposed of in response to the COVID-19 pandemic, these institutions should reimburse the funding agencies for this fiscal waste instead of seeking compensation for losses incurred.

Furthermore, the Congressional Research Service has found that during the COVID-19 pandemic, "Suspending research may result in additional costs for activities such as animal care," and "[r]estarting research, when conditions permit, may also incur costs for staff time and supplies to ... reestablish laboratory animal populations." Taxpayers should not be responsible for the additional costs associated with "reestablishing laboratory animal populations," since these institutions deemed many of them extraneous to the experiments and because repopulating animals in laboratories at taxpayers' expense would appear to violate the aforementioned federal regulations and policies that mandate minimizing the use of animals in experiments.

Given this new supplementary information, we urge your office to investigate and follow up on our full request detailed in our HHS-OIG complaint dated June 15, 2020, and our subsequent NIH OMA complaints dated February 17, 2021, and November 18, 2021. If noncompliance is corroborated, we ask that you ensure that the experimenters adhere to federal mandates to reduce and/or replace the use of animals in experiments. Specifically, there is no justification for continuing to waste public resources to support activities related to the acquisition, breeding, confinement, maintenance, repopulation, and/or experimentation of animals in laboratories who are deemed extraneous, nonessential, noncritical, or described using similar terminology and subsequently killed.

You can contact me at ShriyaS@peta.org. We look forward to your reply regarding this important matter. Thank you.

Sincerely yours,

Shriya Swaminathan Research Associate

International Laboratory Methods

Laboratory Investigations Department

²²Congressional Research Service. Effects of COVID-19 on the federal research and development enterprise. April 10, 2020. Accessed March 10, 2022. https://crsreports.congress.gov/product/pdf/R/R46309