



PEOPLE FOR
THE ETHICAL
TREATMENT
OF ANIMALS

March 15, 2021

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

Via e-mail: deborah.kearse@nih.gov; janet.shoemaker@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) and our more than 6.5 million members and supporters to share new information pertinent to our February 17, 2021, letter to Meredith Stein, director of the Office of Management Assessment (OMA),¹ which was assigned the case number 2021-017 by the Division of Program Integrity, and our June 15, 2020, letter to the U.S. Department of Health and Human Services (HHS) Office of Inspector General (OIG).²

Based on the information in those complaints and the new information presented below, we respectfully urge your office to investigate, assess, and take corrective action regarding the apparent egregious waste of National Institutes of Health (NIH) research funding and the apparent failure of NIH-funded protocols to reduce and replace the use of animals in experiments as required by federal provisions.

New Information to Supplement PETA's Complaints

According to documents received by PETA through Rhode Island Access to Public Records Act (APRA) requests, the University of Rhode Island (URI) euthanized animals deemed extraneous in response to COVID-19, contrary to the school's public denial of this practice last year.³ The animals were assigned to a National Heart, Lung, and Blood Institute (NHLBI)-funded protocol conducted by URI's Richard Clements, titled "Surgical Cardioprotection through BKCa-Dependent Modulation of Mitochondrial

¹PETA. (2021, February 17). *Follow-up letter to the OMA*. <https://www.peta.org/wp-content/uploads/2021/02/2021-02-17-Follow-up-letter-to-OMA-HHS.pdf>

²PETA. (2020, June 15). *Request to the HHS OIG regarding COVID-19 contingency plans at U.S. universities*. <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>

³Nunes, R. (2020, September 15). *URI fires back against 'baseless' animal euthanasia allegations*. Patch.com. <https://patch.com/rhode-island/narragansett/uri-fires-back-against-baseless-animal-euthanasia-allegations>

Washington, D.C.
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

Berkeley
2855 Telegraph Ave.
Ste. 301
Berkeley, CA 94705
510-763-PETA

Info@peta.org
PETA.org

Affiliates:

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

Supercomplexes” (project number 5R01HL135236-02),^{4,5} which in FY2019 received \$164,428 in taxpayer money from the agency.

Per its COVID-19 response plan, URI instructed staff to “draw down [their] research and campus-based scholarly activities”⁶ and stated, “Non-critical research should be curtailed as much as possible”⁷—both of which led to the apparent destruction of animals whom URI deemed non-essential. The school’s “Lab Animal COVID-19 Emergency Procedures” guideline also gave explicit instructions regarding the culling of animals deemed extraneous in response to COVID-19, telling experimenters to “[e]uthanize all old breeders,” “[c]onsider euthanizing males if there are several of the same strain,” and “[e]uthanize or separate extra breeders.”⁸ E-mail correspondence obtained by PETA through APRA requests, with respect to Clements’ mice and involving a URI research technician, mentions “culling old breeders,”⁹ referring to euthanizing elderly animals deemed extraneous in response to COVID-19.

The fact that the laboratory led by Clements had unnecessary, non-essential, noncritical, or extraneous animals in the first place should raise significant red flags, especially since his experiments are funded by taxpayers, who should not have to foot the bill for such waste.

Clements’ NHLBI-Funded Protocol Failed to Reduce and Replace the Use of Animals

The presence of any unnecessary, non-essential, noncritical, or extraneous animals in NHLBI-funded experiments led by Clements flies in the face of existing regulations designed to minimize the use of animals in experiments.

NIH-supported language requiring the minimization of the experimental use of animals is 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

⁴NIH. (n.d.). *Surgical cardioprotection through BKCA-dependent modulation of mitochondrial supercomplexes*. Project number: 5R01HL135236-02. Research Portfolio Online Reporting Tools (RePORT): Project Information. https://projectreporter.nih.gov/project_info_details.cfm?aid=9744774&icde=53799442

⁵URI. (2019, February). *IACUC protocol/three year renewal form*. This was obtained through an APRA request and includes records from four URI research protocols, including IACUC protocol #AN1920-007.

https://www.peta.org/wp-content/uploads/2021/03/2021-02-16-Records-from-URI-4-research-protocols.msg_.pdf

⁶URI. (2020, June 3). *Transition from phase 2 to phase 3: URI research resumption plan*.

<https://web.uri.edu/research-admin/externalrelations/news/transition-from-phase-2-to-phase-3-uri-research-resumption-plan/>

⁷URI. (n.d.). *COVID-19 laboratory research*.

<https://web.uri.edu/research-admin/externalrelations/news/covid-19-laboratory-research/>

⁸URI. (n.d.). *Lab animal COVID-19 emergency procedures*. This was obtained through an APRA request.

<https://www.peta.org/wp-content/uploads/2021/03/20201231122934309.pdf>

⁹URI. (n.d.). *Subject: Re: F333/Protocol AN1920-007/weaning errors*. This was obtained through an APRA request.

<https://www.peta.org/wp-content/uploads/2021/03/20201231122934309.pdf>

... use of *research or testing methods that limit the use of animals* or limit animal distress [*emphasis added*].”¹⁰

- The NIH 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*].”¹¹
- 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*].”¹²
- Appendix B of 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*].”¹³

When Clements, an NHLBI-funded experimenter, buys, breeds, traps, and/or uses animals who at any time—not just during the COVID-19 pandemic—can be deemed unnecessary, non-essential, noncritical, or extraneous or described using similar terminology, he squanders limited research funds, which are provided by taxpayers, and flouts the bedrock “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 unnecessary, non-essential, noncritical, or extraneous animals used in the experiments led by Clements should have been zero from the start since they weren’t relevant to his project. Also, because taxpayer funds were used to acquire, breed, confine, and/or maintain these unnecessary, non-essential, noncritical, or extraneous animals who were then so easily euthanized and disposed of in response to COVID-19, URI should reimburse the NHLBI for this fiscal waste.

Furthermore, the Congressional Research Service has found that during the COVID-19 pandemic, “[s]uspending 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.”¹⁴ Taxpayers and the NHLBI should not be responsible for the additional costs associated with reestablishing laboratory animal populations since universities deemed many of them to be unnecessary, non-essential, noncritical, or extraneous to the experiments and because repopulating animal populations in

¹⁰Health Research Extension Act of 1985, Publ. L. No. 99-158. (1985). <https://olaw.nih.gov/policies-laws/hrea-1985.htm>

¹¹NIH Revitalization Act of 1993, Publ. L. No. 103-43. (1993). <https://grants.nih.gov/grants/olaw/pl103-43.pdf>

¹²National Research Council Committee for the Update of the Guide for the Care and Use of Laboratory Animals. (2011). *Guide for the care and use of laboratory animals*. <https://grants.nih.gov/grants/olaw/guide-for-the-care-and-use-of-laboratory-animals.pdf>

¹³National Research Council Committee for the Update of the Guide for the Care and Use of Laboratory Animals. (2011). *Appendix B: U.S. government principles for the utilization and care of vertebrate animals used in testing, research, and training*. <https://www.ncbi.nlm.nih.gov/books/NBK54048/>

¹⁴Congressional Research Service. (2020, April 10). *Effects of COVID-19 on the federal research and development enterprise*. <https://crsreports.congress.gov/product/pdf/R/R46309>

laboratories at taxpayers' expense would appear to violate the aforementioned federal regulations and policies that mandate minimizing the use of animals in experiments.

Request for Research Accountability and Waste Cutting

Based on this information, we urge your office to investigate the concerns raised in our complaints and, if noncompliance is corroborated, take all corrective action necessary, including cancelling Clements' NHLBI funding and seeking reimbursement of any and all NHLBI funds wasted to acquire, breed, confine, and/or maintain the animals whom he and/or URI deemed unnecessary, non-essential, noncritical, or extraneous or described using similar terminology and then euthanized. As addressed in this letter—and in our February 17, 2021, and June 15, 2020, complaints—we urge you to help ensure compliance with federal mandates to reduce and replace the use of animals in experiments by prohibiting the use of NIH taxpayer-supplied funds for buying, breeding, trapping, and/or using in experiments animals whom universities and/or experimenters may have deemed to be unnecessary, non-essential, noncritical, or extraneous or have described using similar terminology.

You can contact me at ShalinG@peta.org or 757-962-8325. I look forward to your reply regarding this important matter. Thank you.

Sincerely yours,

A handwritten signature in black ink that reads "Shalin G. Gala". The signature is written in a cursive style with a large, sweeping initial "S" that loops under the rest of the name.

Shalin G. Gala
Vice President, International Laboratory Methods
Laboratory Investigations Department