March 15, 2021

Gary H. Gibbons, M.D. Director National Heart, Lung, and Blood Institute

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

Dear Dr. Gibbons:

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 worldwide. On June 15, 2020, we sent a detailed letter to the U.S. Department of Health and Human Services Office of Inspector General urging Principal Deputy Inspector General Christi Grimm to investigate, assess, and take corrective action regarding the apparent egregious waste of National Institutes of Health (NIH) research grants—worth up to billions of taxpayer dollars each year—and the apparent failure of NIH-funded protocols to reduce and replace animal use in experiments as required by federal provisions.<sup>1</sup>

Based on the new information presented below, we urge the National Heart, Lung, and Blood Institute (NHLBI) to cancel the taxpayer funding—amounting to \$164,428 for FY2019—granted to experimenter Richard Clements of the University of Rhode Island (URI) for any and all renewals of his protocols and insist that he reimburses the taxpayer funds used to acquire, breed, confine, and maintain the animals used in experiments whom URI categorized as unnecessary, extraneous, noncritical, non-essential, ramped down, disposable, or nonpriority or described using similar terminology and—according to documents obtained by PETA through Rhode Island Access to Public Records Act (APRA) requests—euthanized in response to COVID-19, contrary to URI's public denial of this practice last year.<sup>2</sup>

**Euthanizing Animals Deemed Extraneous to NHLBI-Funded Experiments Wastes Taxpayer Funds** 

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<sup>&</sup>lt;sup>1</sup>People for the Ethical Treatment of Animals. (2020, June 15). *Request to the U.S. Department of Health and Human Services Regarding the COVID-19 Contingency Plans at U.S. Universities*. <u>https://www.peta.org/wp-content/uploads/2020/06/20-06-15-Request-to-HHS-</u>OIG-regarding-COVID-19-contingency-plans-at-US-universities.pdf

<sup>&</sup>lt;sup>2</sup>Nunes R. (2020, Sept. 15). URI fires back against "baseless" animal euthanasia allegations. *Patch*. <u>https://patch.com/rhode-island/narragansett/uri-fires-back-against-baseless-animal-euthanasia-allegations</u>

Clements conducts the NHLBI-funded protocol titled "Surgical Cardioprotection Through BKCA-Dependent Modulation of Mitochondrial Supercomplexes" (5R01HL135236-02).<sup>3,4</sup> Per its COVID-19 response plan, URI instructed staff to "draw down [their] research and campus-based scholarly activities"<sup>5</sup> and stated that "[n]on-critical research should be curtailed as much as possible"<sup>6</sup>—both of which led to the apparent destruction of animals deemed extraneous by URI. URI'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."<sup>7</sup>

E-mail correspondence obtained by PETA through APRA requests, with respect to Clements' mice and involving a URI research technician, mentions "culling old breeders,"<sup>8</sup> referring to euthanizing elderly animals deemed extraneous in response to COVID-19.

The fact that the laboratory led by Clements had any 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 Animal Use

The presence of any unnecessary, non-essential, noncritical, or extraneous animals in NHLBIfunded 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 present in the Health Research Extension Act of 1985, the National Institutes of Health 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

<sup>6</sup>University of Rhode Island. (n.d.). *Research Resumption Plan*. <u>https://web.uri.edu/research-admin/externalrelations/news/transition-from-phase-2-to-phase-3-uri-research-resumption-plan/</u>

<sup>7</sup>University of Rhode Island. (n.d.). *APRA Documents—Lab Animal COVID-19 Emergency Procedures*. <u>https://www.peta.org/wp-content/uploads/2021/03/20201231122934309.pdf</u>

<sup>&</sup>lt;sup>3</sup>NIH. (n.d.). Surgical Cardioprotection Through BKCA-Dependent Modulation of Mitochondrial Supercomplexes. *Project Number: 5R01HL135236-02.* Research Portfolio Online Reporting Tools (RePORT): Project Information. <u>https://projectreporter.nih.gov/project\_info\_details.cfm?aid=9744774&icde=53799442</u>

<sup>&</sup>lt;sup>4</sup>University of Rhode Island. (n.d.). FOIA Documents—Records From URI 4 Research Protocols. IACUC Protocol # AN1920-007. <u>https://www.peta.org/wp-content/uploads/2021/03/2021-02-16-Records-from-URI-4-research-protocols.msg\_.pdf</u>

<sup>&</sup>lt;sup>5</sup> University of Rhode Island. (n.d.). *COVID-19 Laboratory Research*. <u>https://web.uri.edu/research-admin/externalrelations/news/covid-19-laboratory-research/</u>

<sup>&</sup>lt;sup>8</sup>University of Rhode Island. (n.d.). *APRA Documents—Email Correspondences. Sub: F333/Protocol AN 1920-007* /Weaning Errors. <u>https://www.peta.org/wp-content/uploads/2021/03/20201231122934309.pdf</u>

... use of *research or testing methods that limit the use of animals* or limit animal distress" [*emphasis added*].<sup>9</sup>

- 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].<sup>10</sup>
- 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*].<sup>11</sup>
- 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*].<sup>12</sup>

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 (CRS) 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."<sup>13</sup> Taxpayers and 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 animals in laboratories at

<sup>&</sup>lt;sup>9</sup>Health Research Extension Act of 1985, Publ. L. No. 99–158. (1985). <u>https://olaw.nih.gov/policies-laws/hrea-1985.htm</u>

<sup>&</sup>lt;sup>10</sup>NIH Revitalization Act of 1993, Publ. L. No. 103–43. (1993). <u>https://grants.nih.gov/grants/olaw/pl103-43.pdf</u> <sup>11</sup>National 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*. <u>https://grants.nih.gov/grants/olaw/guide-for-the-care-and-use-of-laboratory-animals.pdf</u>

<sup>&</sup>lt;sup>12</sup>National 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*. <u>https://www.ncbi.nlm.nih.gov/books/NBK54048/</u>

<sup>&</sup>lt;sup>13</sup>Congressional Research Service. (2020, April 10). *Effects of COVID-19 on the Federal Research and Development Enterprise*. <u>https://crsreports.congress.gov/product/pdf/R/R46309</u>

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 Modernization**

We urge you to cancel the funding granted to Clements' project 5R01HL135236-02 and to seek reimbursement from him for any and all NHLBI funds wasted to acquire, breed, confine and/or maintain the animals he and/or URI deemed unnecessary, non-essential, noncritical, or extraneous or described using similar terminology and then euthanized. Moreover, we encourage NHLBI to redirect the funds it initially granted to Clements instead to focus now on human-relevant, non-animal research methods, as described in PETA's Research Modernization Deal.<sup>14</sup>

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

Sincerely yours,

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

CC: Patricia A. Brown, VMD, MS Director Office of Laboratory Animal Welfare (OLAW) <u>olaw@od.nih.gov; patricia.brown@nih.gov</u>

<sup>&</sup>lt;sup>14</sup>People for the Ethical Treatment of Animals. (2021). *The Research Modernization Deal 2021*. <u>https://www.peta.org/wp-content/uploads/2020/12/PETA-2021-Research-Modernization-Deal.pdf</u>